

US3052312 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:58:24

All time stamps listed in this document are displayed in GMT

US3052312

Form: Participant Creation

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

[Participant ID](#)

US3052312

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

US3052312

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
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	False
Black	False
Asian	False
American Indian or Alaska Native	True
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Mar 2021 16:53:07

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Date of Informed Consent (<i>dd MMM yyyy</i>)	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Mar 2021 16:53:07

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Mar 2021 16:53:07

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Condition	TESTICULAR CANCER
Start date (dd MMM yyyy)	UN UNK 1999
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Condition	AVASCULAR NECROSIS
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Condition	RIGHT HIP REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3052312

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Condition	POLLEN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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) _____

Height (xxx.x) _____

Weight (xxx.x) _____

BMI (xxx.x) _____

BMI units _____

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) _____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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 16:53:07

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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

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 16:53:07

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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 16:53:07

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

What was the participant's randomization number? 109474

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 16:53:07

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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 16:53:07

Generated On: 09 Jun 2021 14:58:24

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 type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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 (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:23
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 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 16:53:07

Generated On: 09 Jun 2021 14:58:24

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 16:53:07

Generated On: 09 Jun 2021 14:58:24

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) 11:36 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 11:36

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 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

11:26 (24 HR)

Collection date and time (derived)

28 AUG 2020 11:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	28 AUG 2020 11:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 11:56

PC Close Date & Time

28 AUG 2020 14:26

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 98.7 °F

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

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

PC Time Stamp	28 AUG 2020 15:58
PC Open Date & Time	28 AUG 2020 15:21
PC Close Date & Time	29 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 15:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 18:12

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 18:28

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 21:24

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 ☒

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

03 SEP 2020 06:50

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

03 SEP 2020 22:06

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 11:56

PC Close Date & Time

28 AUG 2020 14:26

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 15:59

PC Open Date & Time

28 AUG 2020 15:21

PC Close Date & Time

29 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 15:23

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 17:55

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 18:29

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:23

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 06:50

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:57

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 11:56

PC Close Date & Time

28 AUG 2020 14:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 15:59
PC Open Date & Time	28 AUG 2020 15:21
PC Close Date & Time	29 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 ☒

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 15:23
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:55
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 ☒

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 18:29
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:23
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 ☒

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 06:50
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:57
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3052312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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 LEFT MESSAGE

If Contact Not Made, please provide Comments

US3052312

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

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 (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	09:34 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 09:34
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

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 (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 11:19
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3052312

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

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.

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

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) 10:47 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 10:47

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

What was the frequency of the study treatment dosing? ONCE

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

US3052312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	25 SEP 2020 10:32

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:35	25 SEP 2020 10:35
Nasopharyngeal Swab 2	No		

US3052312

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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

98.3 °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

25 SEP 2020 11:24

PC Open Date & Time

25 SEP 2020 11:07

PC Close Date & Time

25 SEP 2020 13:37

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

97.3 °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

25 SEP 2020 19:56

PC Open Date & Time

25 SEP 2020 14:32

PC Close Date & Time

26 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:53

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:17

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 17:29

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

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

98.4 °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

29 SEP 2020 19:38

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 20:03

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 20:19

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 11:24

PC Open Date & Time

25 SEP 2020 11:07

PC Close Date & Time

25 SEP 2020 13:37

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

25 SEP 2020 19:57

PC Open Date & Time

25 SEP 2020 14:32

PC Close Date & Time

26 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 12:53

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 20:18

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 17:29

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 19:38

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 20:03

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:20

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 11:25
PC Open Date & Time	25 SEP 2020 11:07
PC Close Date & Time	25 SEP 2020 13:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 19:58
PC Open Date & Time	25 SEP 2020 14:32
PC Close Date & Time	26 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 ☒

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:18
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 ☒

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 17:29
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:38
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 20:04
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 ☒

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:20
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3052312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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 LEFT MESSAGE

If Contact Not Made, please provide Comments

US3052312

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 16:53:18

Generated On: 09 Jun 2021 14:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	14:23 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 14:23
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052312

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:18

Generated On: 09 Jun 2021 14:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3052312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	15:58 (24 HR)
Collection date and time (derived)	23 OCT 2020 15:58

US3052312

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:08

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 07:01:46

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

04 NOV 2020 07:42:00

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 08:00:16

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <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)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
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 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"/>

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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	24 NOV 2020 16:18:28
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <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)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	True
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 DEC 2020 15:19:31
Patient Cloud Open Date & Time	29 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	120 of 2575

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

Date and time of submission

06 DEC 2020 12:12:27

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

Date and time of submission

15 DEC 2020 19:08:53

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

Date and time of submission

20 DEC 2020 13:44:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

Date and time of submission

28 DEC 2020 20:56:37

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 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	04 JAN 2021 19:36:08
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 19:43:22

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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	18 JAN 2021 00:00:31
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 09:50:17

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 FEB 2021 17:30:51
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 20:31:02
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

14 FEB 2021 18:46:49

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 FEB 2021 22:12:40
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 05:02:39

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 00:02:45

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

14 MAR 2021 13:18:20

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 18:19:57

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 12:01:04

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 21:09:47

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 21:42:58

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 APR 2021 01:21:51
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:42:11

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

Date and time of submission

02 MAY 2021 09:17:32

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
---	--

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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°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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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°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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	02 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 <input type="checkbox"/>
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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

US3052312

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:58:24

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		28 FEB 2021 05:02:30

US3052312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052312

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

If Contact Not Made, please provide Comments

US3052312

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052312

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT VOICEMAIL

If Contact Not Made, please provide Comments

US3052312

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

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

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

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

Folder OID	VISIT4
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US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 14:21
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052312

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3052312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	15:11 (24 HR)
Collection date and time (derived)	19 MAR 2021 15:11

US3052312

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 13:52:22

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 13:52:22

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Date of Contact	2 FEB 2021
Time of Contact	14:35
Date and Time of Contact (derived)	2 FEB 2021 14:35
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Symptom Day

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

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	26 JAN 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	27 JAN 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

Shortness of Breath	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	28 JAN 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

Shortness of Breath	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	29 JAN 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

Shortness of Breath	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	30 JAN 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

Shortness of Breath	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	31 JAN 2021
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

Shortness of Breath	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	1 FEB 2021	
Assessment Not Done	False	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	4 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	5 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	6 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.6 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 ☐

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	7 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	8 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

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	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	9 FEB 2021
------	------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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Form: Symptom Log (13)

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

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (14)

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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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	10 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	11 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (15)

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	12 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 09 Jun 2021 14:58:24

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

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Form: Symptom Log (16)

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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 ☐

US3052312

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Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	13 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.9 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

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Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.4 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	15 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 checked="" 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 type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

	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	16 FEB 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 15:26:31

Generated On: 09 Jun 2021 14:58:24

Date of Visit	4 FEB 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	4 FEB 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Apr 2021 13:52:22

Generated On: 09 Jun 2021 14:58:24

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3052312

Folder: Covid-19 Assessment 04 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 20:36:19

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 15:26:32

Generated On: 09 Jun 2021 14:58:24

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	6 FEB 2021
Day 5	Yes	8 FEB 2021
Day 7	Yes	10 FEB 2021
Day 9	Yes	12 FEB 2021
Day 14	Yes	17 FEB 2021
Day 21	Yes	24 FEB 2021
Day 28	No	

US3052312

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 FEB 2021
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 16:30
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052312

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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

US3052312

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

4 FEB 2021

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 14:19
Height (xxx.x)	74 in
Weight (xxx.x)	242 lb
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3052312

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 FEB 2021

US3052312

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

Visit date (dd MMM yyyy)	16 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3052312

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 19:00:09

Generated On: 09 Jun 2021 14:58:24

Date of updated informed consent (<i>dd MMM yyyy</i>)	16 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>)	16 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

US3052312

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Height	188 cm
Weight	111 kg
BMI (xxx.x)	31.40561

US3052312

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Height	188 cm
Weight	111 kg
BMI (xxx.x)	31.40561
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)	16 JAN 2021
Time of assessment (00:00-23:59)	13:14 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 13:14
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3052312

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Height	188 cm
Weight	111 kg
BMI (xxx.x)	31.40561
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)	16 JAN 2021
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 14:43
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3052312

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

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 JAN 2021

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

US3052312

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

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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) 16 JAN 2021

What was the treatment time? (00:00-23:59) 14:06 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 14:06

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

US3052312

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 JAN 2021

Collection time (00:00-23:59)

15:58 (24 HR)

Collection date and time (derived)

16 JAN 2021 15:58

US3052312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

Collection date (dd MMM yyyy)	16 JAN 2021
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Collection time (00:00 - 23:59)	14:01
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Collection Date and Time (derived)	16 JAN 2021 14:01
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US3052312

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

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3052312

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 20:43:40

Generated On: 09 Jun 2021 14:58:24

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 (dd MMM yyyy)	12 FEB 2021
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 12:55
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 20:43:40

Generated On: 09 Jun 2021 14:58:24

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 (dd MMM yyyy)	12 FEB 2021
Time of assessment (00:00-23:59)	13:55 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 13:55
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3052312

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3052312

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

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) 12 FEB 2021

What was the treatment time? (00:00-23:59) 13:16 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 13:16

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

US3052312

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3052312

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:41

Generated On: 09 Jun 2021 14:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:21 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 14:21
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	85 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3052312

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:43:40

Generated On: 09 Jun 2021 14:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3052312

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:40

Generated On: 09 Jun 2021 14:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	15:11 (24 HR)
Collection date and time (derived)	19 MAR 2021 15:11

US3052312

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 20:31:42

Generated On: 09 Jun 2021 14:58:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

AEID

Adverse event

SINUS INFECTION

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)

24 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

AEID	USA-US117-2021-MRNA-1273-P30 1000009
Adverse event	SEPTIC RIGHT KNEE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	31 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	29 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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	

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

SUBJECT HAD A COVID NASAL
SWAB ON 27JAN2021 AND
31JAN2021 BOTH WERE
NEGATIVE. SUBJECT HAD
BLOOD CULTURES DRAWN
EVERYDAY HE WAS IN THE
HOSPITAL. SUBJECT WAS NOT
GIVEN ANY SURGERY. HE WAS
ON IV DRIP ALL 5 DAYS.
SUBJECT DOES NOT
REMEMBER THE NAMES OF
THE MEDICATIONS. MEDICAL
RECORDS HAVE BEEN
REQUESTED.

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

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

Yes ☒

No ☐

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

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 160

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 16:53:07

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 15:26:30

Generated On: 09 Jun 2021 14:58:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3052312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 15:26:30

Generated On: 09 Jun 2021 14:58:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 FEB 2021	ENDOSCOPIC PROCEDURE FOR VOCAL CORDS	Diagnostic	

US3052312

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:58:24

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

US3052312

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:58:24

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 ☐

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:08:09

Generated On: 09 Jun 2021 14:58:24

SAEID	USA-US117-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:08:09

Generated On: 09 Jun 2021 14:58:24

SAEID	USA-US117-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	19/APR/2021 13:08
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

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:08:09

Generated On: 09 Jun 2021 14:58:24

SAEID	USA-US117-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	YAA
Investigator's Last Name	OPPONG
Site Address: Street	1565 PURDUE DRIVE
Site Address: City	FAYETTEVILLE
Site Address: State	NC
Site Address: Postal Code	28314
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	27/APR/2021 14:50
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

US3052312 (Prod: Carolina Institute for Clinical Research - M3 Wake Research)

US3052312

Form: Participant Creation

Generated On: 09 Jun 2021 14:58:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'US3052312'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 14:24:40

US3052312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:34
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:45

US3052312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:34
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 14:24:41

US3052312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:34
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:45

US3052312

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:34
Data hard locked.		03 Apr 2021 08:27:47
User entered 'SCRN'	System	01 Sep 2020 19:21:45

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 14:24:42

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '51'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User entered 'YEARS'	System	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User entered '51'	System	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:58:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:05:52
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:13:35

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User entered 'Aug 2020'	System	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User entered '2020'	System	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Amendment 3 (3)'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:57:34

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 14:24:41

US3052312

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:58:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:00
Data hard locked.		03 Apr 2021 08:27:47
User entered 'l'		28 Aug 2020 19:57:41

US3052312

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:06
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:57:41

US3052312

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:58:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:10
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:09:31

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Testicular neoplasms malignant, PT: Testis cancer, LLT: Testicular cancer - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:10:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:10:51
Data point term sent to Coder	System	01 Sep 2020 19:10:38
User entered 'Testicular Cancer'	(b) (4), (b) (6)	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'UN UNK 1999'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 1999'	System	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '1999'	System	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 2000'	System	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '2000'	System	01 Sep 2020 19:10:23

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 16:29:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 16:29:47
Data point term sent to Coder	System	22 Mar 2021 16:28:24
User entered 'AVASCULAR NECROSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:28:12
Data point term sent to Coder	System	22 Mar 2021 16:27:23
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 16:26:42
User entered 'VASCULAR NECROSIS' reason for change: Data Entry Error		22 Mar 2021 16:26:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:12:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:12:46
Data point term sent to Coder	System	01 Sep 2020 19:11:40
User entered 'Avascular necrosis'	(b) (4), (b) (6)	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'No (N)'	(b) (4)	01 Sep 2020 19:11:35
	(b) (4), (b) (6)	

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'UN UNK 2004'	(b) (4), (b) (6)	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 2004'	System	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '2004'	System	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 2004'	System	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '2004'	System	01 Sep 2020 19:11:35

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:13:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 19:13:49
Data point term sent to Coder	System	01 Sep 2020 19:12:41
User entered 'High cholesterol'	(b) (4), (b) (6)	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 2019'	System	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '2019'	System	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered empty.	System	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered empty.	System	01 Sep 2020 19:11:54

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User closed query 'Per CDM DM CLR (RQ)- Per response however kindly clarify for which associated condition was this procedure carried out else amend as appropriate.' (Site from DM).		09 Apr 2021 22:10:02
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
Query 'Per CDM DM CLR (RQ)- Per response however kindly clarify for which associated condition was this procedure carried out else amend as appropriate.' answered with 'vascular necrosis was the associated condition' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:14:06
User opened query 'Per CDM DM CLR (RQ)- Per response however kindly clarify for which associated condition was this procedure carried out else amend as appropriate.' (Site from DM).		02 Apr 2021 19:57:39
User closed query 'Per CDM, DM CLR RQ: Response noted. Please ensure the condition which led to this procedure is recorded as a separate entry on the MH page or provide clarification. ' (Site from DM).		02 Apr 2021 19:57:39
Query 'Per CDM, DM CLR RQ: Response noted. Please ensure the condition which led to this procedure is recorded as a separate entry on the MH page or provide clarification. ' answered with 'verified and updated' (Site from DM).		26 Mar 2021 19:45:04
User opened query 'Per CDM, DM CLR RQ: Response noted. Please ensure the condition which led to this procedure is recorded as a separate entry on the MH page or provide clarification. ' (Site from DM).		23 Mar 2021 15:49:16
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).		23 Mar 2021 15:49:16
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'Reviewed and updated' (Site from DM).		22 Mar 2021 16:26:13

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 14:09:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 18:48:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	26 Oct 2020 18:48:49
Data point term sent to Coder	System	26 Oct 2020 17:46:10
User entered 'Right hip replacement'	Avia McClain-Stocker	26 Oct 2020 17:45:56
	(b) (4)	

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'un UNK 2004'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	Avia McClain-Stocker	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'No (N)'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:45:56
	(b) (4)	

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'un UNK 2004'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 2004'	System	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '2004'	System	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 2004'	System	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '2004'	System	26 Oct 2020 17:45:56

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Pollen allergy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 18:51:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 18:51:21
Data point term sent to Coder	System	26 Oct 2020 17:47:12
User entered 'pollen allergy'	Avia McClain-Stocker	26 Oct 2020 17:46:20
	(b) (4)	

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'un UNK 1974'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	Avia McClain-Stocker	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:46:20
	(b) (4)	

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	Avia McClain-Stocker	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '0'	Avia McClain-Stocker	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered 'Jan 1974'	System	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered '1974'	System	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered empty.	System	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
User entered empty.	System	26 Oct 2020 17:46:20

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User entered empty.	System	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16
DataPoint set to visible.	System	28 Aug 2020 19:57:41

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16
DataPoint set to visible.	System	28 Aug 2020 19:57:41

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User entered empty.	System	01 Sep 2020 19:21:16
DataPoint set to visible.	System	28 Aug 2020 19:57:41

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User entered empty.	System	01 Sep 2020 19:21:16
DataPoint set to visible.	System	28 Aug 2020 19:57:41

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User entered empty.	System	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.	(b) (4), (b) (6)	07 Apr 2021 07:06:26
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User entered empty.	System	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User entered empty.	System	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47
User entered empty.	System	01 Sep 2020 19:21:16

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47

US3052312

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:26
Data hard locked.		03 Apr 2021 08:27:47

US3052312

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:37
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:15:08

US3052312

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:37
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:15:08

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

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 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:58:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:52:00
Data hard unlocked.		07 Apr 2021 07:06:46
Data hard locked.		03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Sep 2020 19:12:41

US3052312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:32

US3052312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:32

US3052312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:21:32

US3052312

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'VISIT1'	System	01 Sep 2020 19:21:32

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 14:24:43

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '109474'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 14:24:43

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 14:24:43

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

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 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:12

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

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 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:12

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:12

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:12

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:12

US3052312

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:58:24

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:47:35
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:24:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:24:51

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
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. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:21:30
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. 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 17:47:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:47:45
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. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:04:02
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 17:47:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
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. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:21:30
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. 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 17:47:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:47:45
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. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:04:02
User entered empty.		01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 17:47:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
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).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 05:22:01
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.' answered with 'Pre-Dose vitals not recorded in source documents' (Site from DM).	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:48:22
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 07:04:13
User entered 'No (N)'		01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered empty.	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	01 Sep 2020 19:20:59
	(b) (4), (b) (6)	

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	01 Sep 2020 19:20:59
	(b) (4), (b) (6)	

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4)	01 Sep 2020 19:20:59
	(b) (4), (b) (6)	

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered empty.	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered empty.	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered empty.	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered empty.	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
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. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:21:30
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. 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 17:47:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:47:45
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. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 07:04:02
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	26 Oct 2020 17:47:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User accepted default value 'Post-Dose (POSTDOSE)'		01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '12:23'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered '28 Aug 2020 12:23'	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '76'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'bpm'	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '12'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'breaths/min'	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '122'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'mmHg'	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '84'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'mmHg'	System	01 Sep 2020 19:20:59

US3052312

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
DataPoint Verified.	(b) (4)	10 Nov 2020 19:27:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 12:46:45
User entered 'Yes (Y)'	Avia McClain-Stocker	01 Sep 2020 19:16:34
	(b) (4)	
	(b) (4), (b) (6)	

US3052312

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
DataPoint Verified.	(b) (4)	10 Nov 2020 19:27:22
User entered empty; reason for change Data Entry Error	Avia McClain-Stocker	20 Oct 2020 12:46:45
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 19:16:34

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

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 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	(b) (4) Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '11:36'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered '28 Aug 2020 11:36'	System	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) amy sheets (b) (4) (b) (4)	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'ONCE'	System	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 19:58:11

US3052312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:18:42

US3052312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:18:42

US3052312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '11:26'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:18:42

US3052312

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered '28 Aug 2020 11:26'	System	01 Sep 2020 19:18:42

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	01 Sep 2020 19:19:26
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	01 Sep 2020 19:19:26
User entered '11:30' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 19:19:26
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	01 Sep 2020 19:18:56
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered '28 Aug 2020 11:30'	System	01 Sep 2020 19:19:26
User entered empty.	System	01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered empty.	System	01 Sep 2020 19:18:56

US3052312

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:22:40

US3052312

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Apr 2021 04:15:15
User entered 'I'	System	25 Sep 2020 15:22:40

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 11:56'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:58:44', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4d495895-2d13-46a0-855a-039fb18b4b37'	System	28 Aug 2020 19:59:00
User entered 'Yes (Y)'	System	28 Aug 2020 19:59:00

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:58:48', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4d495895-2d13-46a0-855a-039fb18b4b37'	System	28 Aug 2020 19:59:00
User entered '98.7'	System	28 Aug 2020 19:59:00

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:58:53', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4d495895-2d13-46a0-855a-039fb18b4b37'	System	28 Aug 2020 19:59:00
User entered 'No (N)'	System	28 Aug 2020 19:59:00

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:58:59', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4d495895-2d13-46a0-855a-039fb18b4b37'	System	28 Aug 2020 19:59:00
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 19:59:00

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 15:21'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 2'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:24:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '64967017-4089-42bf-b4f5-2d469885172e' User entered 'Yes (Y)'	System	29 Aug 2020 19:25:10
	System	29 Aug 2020 19:25:10

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:24:57', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '64967017-4089-42bf-b4f5-2d469885172e' User entered '97.9'	System	29 Aug 2020 19:25:10
	System	29 Aug 2020 19:25:10

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:25:03', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '64967017-4089-42bf-b4f5-2d469885172e'	System	29 Aug 2020 19:25:10
User entered 'No (N)'	System	29 Aug 2020 19:25:10

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:25:06', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '64967017-4089-42bf-b4f5-2d469885172e' User entered '29 Aug 2020 15:25'	System	29 Aug 2020 19:25:10
	System	29 Aug 2020 19:25:10

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 3'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T18:12:47', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f463ba45-696e-4cba-bb32-4f9d3df75b7c' User entered 'Yes (Y)'	System	30 Aug 2020 22:13:02
	System	30 Aug 2020 22:13:02

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T18:12:52', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f463ba45-696e-4cba-bb32-4f9d3df75b7c' User entered '97.9'	System	30 Aug 2020 22:13:02
	System	30 Aug 2020 22:13:02

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T18:12:56', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f463ba45-696e-4cba-bb32-4f9d3df75b7c'	System	30 Aug 2020 22:13:02
User entered 'No (N)'	System	30 Aug 2020 22:13:02

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T18:12:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f463ba45-696e-4cba-bb32-4f9d3df75b7c' User entered '30 Aug 2020 18:12'	System	30 Aug 2020 22:13:02
	System	30 Aug 2020 22:13:02

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 4'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:28:42', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e256000e-fe72-4605-a5be-d7e265f80176' User entered 'Yes (Y)'	System	31 Aug 2020 22:28:53
	System	31 Aug 2020 22:28:53

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:28:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e256000e-fe72-4605-a5be-d7e265f80176' User entered '98.0'	System	31 Aug 2020 22:28:53
	System	31 Aug 2020 22:28:53

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:28:49', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e256000e-fe72-4605-a5be-d7e265f80176' User entered 'No (N)'	System	31 Aug 2020 22:28:53
	System	31 Aug 2020 22:28:53

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:28:52', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e256000e-fe72-4605-a5be-d7e265f80176' User entered '31 Aug 2020 18:28'	System	31 Aug 2020 22:28:53
	System	31 Aug 2020 22:28:53

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 5'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:24:04', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '393ca198-740d-4944-9a74-12b729b42a73'	System	02 Sep 2020 01:24:21
User entered 'Yes (Y)'	System	02 Sep 2020 01:24:21

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:24:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '393ca198-740d-4944-9a74-12b729b42a73' User entered '97.9'	System	02 Sep 2020 01:24:21
	System	02 Sep 2020 01:24:21

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:24:11', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '393ca198-740d-4944-9a74-12b729b42a73'	System	02 Sep 2020 01:24:21
User entered 'No (N)'	System	02 Sep 2020 01:24:21

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:24:19', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '393ca198-740d-4944-9a74-12b729b42a73'	System	02 Sep 2020 01:24:21
User entered '01 Sep 2020 21:24'	System	02 Sep 2020 01:24:21

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 6'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:49:42', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1f80f4cb-bc7d-4ea4-a8cc-be1edb8c010a' User entered 'Yes (Y)'	System	03 Sep 2020 10:50:09
	System	03 Sep 2020 10:50:09

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:49:53', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1f80f4cb-bc7d-4ea4-a8cc-be1edb8c010a' User entered '98.2'	System	03 Sep 2020 10:50:09
	System	03 Sep 2020 10:50:09

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:02', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1f80f4cb-bc7d-4ea4-a8cc-be1edb8c010a'	System	03 Sep 2020 10:50:09
User entered 'No (N)'	System	03 Sep 2020 10:50:09

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:06', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1f80f4cb-bc7d-4ea4-a8cc-be1edb8c010a' User entered '03 Sep 2020 06:50'	System	03 Sep 2020 10:50:09
	System	03 Sep 2020 10:50:09

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 7'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T22:06:14', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b3cd6088-030a-4c97-b122-1b7b28e4fe8b' User entered 'Yes (Y)'	System	04 Sep 2020 02:06:27
	System	04 Sep 2020 02:06:27

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T22:06:18', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b3cd6088-030a-4c97-b122-1b7b28e4fe8b' User entered '97.4'	System	04 Sep 2020 02:06:27
	System	04 Sep 2020 02:06:27

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T22:06:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b3cd6088-030a-4c97-b122-1b7b28e4fe8b' User entered 'No (N)'	System	04 Sep 2020 02:06:27
	System	04 Sep 2020 02:06:27

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T22:06:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b3cd6088-030a-4c97-b122-1b7b28e4fe8b' User entered '03 Sep 2020 22:06'	System	04 Sep 2020 02:06:27
	System	04 Sep 2020 02:06:27

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 11:56'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4f1191ee-d2ae-4473-aa28-da0c6a2a5c12'	System	28 Aug 2020 19:59:24
User entered 'None (1)'	System	28 Aug 2020 19:59:24

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:11', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4f1191ee-d2ae-4473-aa28-da0c6a2a5c12'	System	28 Aug 2020 19:59:24
User entered 'No (N)'	System	28 Aug 2020 19:59:24

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:13', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4f1191ee-d2ae-4473-aa28-da0c6a2a5c12'	System	28 Aug 2020 19:59:24
User entered 'No (N)'	System	28 Aug 2020 19:59:24

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:18', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4f1191ee-d2ae-4473-aa28-da0c6a2a5c12'	System	28 Aug 2020 19:59:24
User entered 'None (1)'	System	28 Aug 2020 19:59:24

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:21', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4f1191ee-d2ae-4473-aa28-da0c6a2a5c12'	System	28 Aug 2020 19:59:24
User entered '28 Aug 2020 15:59'	System	28 Aug 2020 19:59:24

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 15:21'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 2'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:01', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '52bcc707-2c75-4a81-9b07-e9e47928eb90'	System	29 Aug 2020 19:23:18
User entered 'None (1)'	System	29 Aug 2020 19:23:18

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:05', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '52bcc707-2c75-4a81-9b07-e9e47928eb90'	System	29 Aug 2020 19:23:18
User entered 'No (N)'	System	29 Aug 2020 19:23:18

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '52bcc707-2c75-4a81-9b07-e9e47928eb90'	System	29 Aug 2020 19:23:18
User entered 'No (N)'	System	29 Aug 2020 19:23:18

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:13', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '52bcc707-2c75-4a81-9b07-e9e47928eb90'	System	29 Aug 2020 19:23:18
User entered 'None (1)'	System	29 Aug 2020 19:23:18

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:17', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '52bcc707-2c75-4a81-9b07-e9e47928eb90'	System	29 Aug 2020 19:23:18
User entered '29 Aug 2020 15:23'	System	29 Aug 2020 19:23:18

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 3'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:03', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dda03faa-fe3c-40e5-89bf-f684ab4d7625'	System	30 Aug 2020 21:55:22
User entered 'None (1)'	System	30 Aug 2020 21:55:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:06', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dda03faa-fe3c-40e5-89bf-f684ab4d7625'	System	30 Aug 2020 21:55:22
User entered 'No (N)'	System	30 Aug 2020 21:55:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dda03faa-fe3c-40e5-89bf-f684ab4d7625' User entered 'No (N)'	System	30 Aug 2020 21:55:22
	System	30 Aug 2020 21:55:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:16', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dda03faa-fe3c-40e5-89bf-f684ab4d7625'	System	30 Aug 2020 21:55:22
User entered 'None (1)'	System	30 Aug 2020 21:55:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:19', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dda03faa-fe3c-40e5-89bf-f684ab4d7625'	System	30 Aug 2020 21:55:22
User entered '30 Aug 2020 17:55'	System	30 Aug 2020 21:55:22

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 4'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:28:55', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '6248ad2c-81a8-495c-ae30-fdf9bb095f34'	System	31 Aug 2020 22:29:07
User entered 'None (1)'	System	31 Aug 2020 22:29:07

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:28:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '6248ad2c-81a8-495c-ae30-fdf9bb095f34'	System	31 Aug 2020 22:29:07
User entered 'No (N)'	System	31 Aug 2020 22:29:07

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:01', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '6248ad2c-81a8-495c-ae30-fdf9bb095f34'	System	31 Aug 2020 22:29:07
User entered 'No (N)'	System	31 Aug 2020 22:29:07

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:02', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '6248ad2c-81a8-495c-ae30-fdf9bb095f34' User entered 'None (1)'	System	31 Aug 2020 22:29:07
	System	31 Aug 2020 22:29:07

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:05', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '6248ad2c-81a8-495c-ae30-fdf9bb095f34'	System	31 Aug 2020 22:29:07
User entered '31 Aug 2020 18:29'	System	31 Aug 2020 22:29:07

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 5'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:42', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ae65eae4-f4a2-4b5d-9163-7b30bb06d25b' User entered 'None (1)'	System	02 Sep 2020 01:24:00
	System	02 Sep 2020 01:24:00

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:49', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ae65eae4-f4a2-4b5d-9163-7b30bb06d25b' User entered 'No (N)'	System	02 Sep 2020 01:24:00
	System	02 Sep 2020 01:24:00

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:51', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ae65eae4-f4a2-4b5d-9163-7b30bb06d25b' User entered 'No (N)'	System	02 Sep 2020 01:24:00
	System	02 Sep 2020 01:24:00

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:53', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ae65eae4-f4a2-4b5d-9163-7b30bb06d25b' User entered 'None (1)'	System	02 Sep 2020 01:24:00
	System	02 Sep 2020 01:24:00

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:55', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ae65eae4-f4a2-4b5d-9163-7b30bb06d25b' User entered '01 Sep 2020 21:23'	System	02 Sep 2020 01:24:00
	System	02 Sep 2020 01:24:00

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 6'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:09', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'a9c34291-dc1e-486a-92c0-ac1b32a318b4'	System	03 Sep 2020 10:50:33
User entered 'None (1)'	System	03 Sep 2020 10:50:33

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'a9c34291-dc1e-486a-92c0-ac1b32a318b4' User entered 'No (N)'	System	03 Sep 2020 10:50:33
	System	03 Sep 2020 10:50:33

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:16', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'a9c34291-dc1e-486a-92c0-ac1b32a318b4' User entered 'No (N)'	System	03 Sep 2020 10:50:33
	System	03 Sep 2020 10:50:33

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:26', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'a9c34291-dc1e-486a-92c0-ac1b32a318b4'	System	03 Sep 2020 10:50:33
User entered 'None (1)'	System	03 Sep 2020 10:50:33

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:29', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'a9c34291-dc1e-486a-92c0-ac1b32a318b4' User entered '03 Sep 2020 06:50'	System	03 Sep 2020 10:50:33
	System	03 Sep 2020 10:50:33

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 7'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ed1ae69f-d01c-49a3-90b7-9d1f36178cd9'	System	04 Sep 2020 01:57:39
User entered 'None (1)'	System	04 Sep 2020 01:57:39

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:30', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ed1ae69f-d01c-49a3-90b7-9d1f36178cd9' User entered 'No (N)'	System	04 Sep 2020 01:57:39
	System	04 Sep 2020 01:57:39

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:33', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ed1ae69f-d01c-49a3-90b7-9d1f36178cd9' User entered 'No (N)'	System	04 Sep 2020 01:57:39
	System	04 Sep 2020 01:57:39

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:35', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ed1ae69f-d01c-49a3-90b7-9d1f36178cd9'	System	04 Sep 2020 01:57:39
User entered 'None (1)'	System	04 Sep 2020 01:57:39

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:38', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'ed1ae69f-d01c-49a3-90b7-9d1f36178cd9' User entered '03 Sep 2020 21:57'	System	04 Sep 2020 01:57:39
	System	04 Sep 2020 01:57:39

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 11:56'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 14:26'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:31', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f' User entered 'None (0)'	System	28 Aug 2020 20:00:05
	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:33', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f' User entered 'None (0)'	System	28 Aug 2020 20:00:05
	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:36', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f' User entered 'None (0)'	System	28 Aug 2020 20:00:05
	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:39', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f' User entered 'None (0)'	System	28 Aug 2020 20:00:05
	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:41', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f' User entered 'None (0)'	System	28 Aug 2020 20:00:05
	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:44', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f' User entered 'None (0)'	System	28 Aug 2020 20:00:05
	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:53', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f'	System	28 Aug 2020 20:00:05
User entered 'No (N)'	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-28T15:59:55', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'dadab783-099e-477b-a9ff-ff6f1120a71f' User entered '28 Aug 2020 15:59'	System	28 Aug 2020 20:00:05
	System	28 Aug 2020 20:00:05

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Aug 2020 15:21'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 2'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6' User entered 'None (0)'	System	29 Aug 2020 19:23:48
	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:29', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6' User entered 'None (0)'	System	29 Aug 2020 19:23:48
	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:31', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6' User entered 'None (0)'	System	29 Aug 2020 19:23:48
	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6' User entered 'None (0)'	System	29 Aug 2020 19:23:48
	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:36', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6' User entered 'None (0)'	System	29 Aug 2020 19:23:48
	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:38', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6' User entered 'None (0)'	System	29 Aug 2020 19:23:48
	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:43', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6'	System	29 Aug 2020 19:23:48
User entered 'No (N)'	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-29T15:23:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '74fe35d7-3166-49ca-9698-e1bc8939f0a6' User entered '29 Aug 2020 15:23'	System	29 Aug 2020 19:23:48
	System	29 Aug 2020 19:23:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 3'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:23', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff' User entered 'None (0)'	System	30 Aug 2020 21:55:45
	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:25', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff' User entered 'None (0)'	System	30 Aug 2020 21:55:45
	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:28', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff' User entered 'None (0)'	System	30 Aug 2020 21:55:45
	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:30', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff' User entered 'None (0)'	System	30 Aug 2020 21:55:45
	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:32', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff' User entered 'None (0)'	System	30 Aug 2020 21:55:45
	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:35', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff' User entered 'None (0)'	System	30 Aug 2020 21:55:45
	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:40', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff'	System	30 Aug 2020 21:55:45
User entered 'No (N)'	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-30T17:55:43', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fada0006-33b6-45bb-8be5-8a6c2e5638ff' User entered '30 Aug 2020 17:55'	System	30 Aug 2020 21:55:45
	System	30 Aug 2020 21:55:45

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 4'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2' User entered 'None (0)'	System	31 Aug 2020 22:29:26
	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:10', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2' User entered 'None (0)'	System	31 Aug 2020 22:29:26
	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2' User entered 'None (0)'	System	31 Aug 2020 22:29:26
	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:14', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2' User entered 'None (0)'	System	31 Aug 2020 22:29:26
	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2' User entered 'None (0)'	System	31 Aug 2020 22:29:26
	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:17', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2' User entered 'None (0)'	System	31 Aug 2020 22:29:26
	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2'	System	31 Aug 2020 22:29:26
User entered 'No (N)'	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-08-31T18:29:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '58145d8c-49a1-4695-9622-d09a220acc2' User entered '31 Aug 2020 18:29'	System	31 Aug 2020 22:29:26
	System	31 Aug 2020 22:29:26

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 5'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:25', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered 'None (0)'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:27', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered 'None (0)'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:28', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered 'None (0)'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:30', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered 'None (0)'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:32', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered 'None (0)'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered 'None (0)'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:36', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered 'No (N)'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-01T21:23:38', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '030fbfa3-1b88-4f9d-80f8-161fe2dd9f41' User entered '01 Sep 2020 21:23'	System	02 Sep 2020 01:23:43
	System	02 Sep 2020 01:23:43

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 6'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:32', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9'	System	03 Sep 2020 10:50:48
User entered 'None (0)'	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9'	System	03 Sep 2020 10:50:48
User entered 'None (0)'	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:35', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9' User entered 'None (0)'	System	03 Sep 2020 10:50:48
	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:38', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9' User entered 'None (0)'	System	03 Sep 2020 10:50:48
	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:39', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9' User entered 'None (0)'	System	03 Sep 2020 10:50:48
	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:41', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9' User entered 'None (0)'	System	03 Sep 2020 10:50:48
	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:43', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9'	System	03 Sep 2020 10:50:48
User entered 'No (N)'	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T06:50:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '260f9d83-7e13-4e43-a8f8-0a9ff3ebbc9'	System	03 Sep 2020 10:50:48
User entered '03 Sep 2020 06:50'	System	03 Sep 2020 10:50:48

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 7'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603' User entered 'None (0)'	System	04 Sep 2020 01:57:23
	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:09', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603' User entered 'None (0)'	System	04 Sep 2020 01:57:23
	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:11', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603' User entered 'None (0)'	System	04 Sep 2020 01:57:23
	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:13', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603' User entered 'None (0)'	System	04 Sep 2020 01:57:23
	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:14', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603' User entered 'None (0)'	System	04 Sep 2020 01:57:23
	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603' User entered 'None (0)'	System	04 Sep 2020 01:57:23
	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:19', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603' User entered 'No (N)'	System	04 Sep 2020 01:57:23
	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-03T21:57:21', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f584fbf0-e155-4405-a3b8-0239550f8603'	System	04 Sep 2020 01:57:23
User entered '03 Sep 2020 21:57'	System	04 Sep 2020 01:57:23

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:58:11

US3052312

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:57:23
	(b) (4)	

US3052312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:43:49
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 per source document' (Site from System).	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:57:38
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 17:57:23
User entered '8 Sep 2020'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:57:23

US3052312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:57:23

US3052312

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:57:23
	(b) (4)	

US3052312

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:22:50

US3052312

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User entered 'I'	System	25 Sep 2020 15:22:50

US3052312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:50:02
	(b) (4)	

US3052312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '14 Sep 2020'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:50:02
	(b) (4)	

US3052312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:50:02

US3052312

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'left message'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:50:02
	(b) (4)	

US3052312

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:22:56

US3052312

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:27:47
User entered 'I'	System	25 Sep 2020 15:22:56

US3052312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:49
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:51:45

US3052312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:49
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '21 Sep 2020'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:51:45
	(b) (4)	

US3052312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:49
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:51:45

US3052312

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:49
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:51:45
	(b) (4)	

US3052312

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:49
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4)	
	Stacey Saldua (b) (4)	25 Sep 2020 15:23:04
	(b) (4)	

US3052312

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:47:49
User entered 'I'	System	25 Sep 2020 15:23:04

US3052312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 05:37:45
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:34
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 11:57:39
User entered 'Yes (Y)'	Stacey Saldua (b) (4) (b) (4)	25 Sep 2020 15:23:16

US3052312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '25 Sep 2020'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:23:16
	(b) (4)	

US3052312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Clinic (Clinic)'	(b) (4) Stacey Saldua (b) (4) (b) (4)	25 Sep 2020 15:23:16

US3052312

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 15:23:16

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '25 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '09:34'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 09:34'	System	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '37.1' C	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '66'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '12'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '118'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '80'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

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 17:54:43

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '25 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '11:19'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 11:19'	System	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '98.3' F	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '62'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '15'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '101'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:55:26
	(b) (4)	

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '66'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[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 17:55:26

US3052312

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:23:25
	(b) (4)	

US3052312

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '25 Sep 2020'	(b) (4)	
	Stacey Saldua (b) (4)	25 Sep 2020 15:23:25
	(b) (4)	

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered empty.	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered empty.	(b) (4) Stacey Saldua (b) (4) (b) (4)	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[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 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User closed query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 25SEP2020 is not completed in EDC.. Please complete' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:58:41
Query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 25SEP2020 is not completed in EDC.. Please complete' answered with 'completed' (Site from DM).	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:55:50
User opened query 'Per GCL Lab Recon: it appears GCL has a nasopharyngeal sample with date of 25SEP2020 is not completed in EDC.. Please complete' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:45:51
User entered '25 Sep 2020'	Stacey Saldua (b) (4) (b) (4)	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '10:47'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[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 10:47'	System	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) Stacey Saldua (b) (4)	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[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
User entered 'ONCE'	System	25 Sep 2020 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

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 15:23:48

US3052312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:13

US3052312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '25 Sep 2020'	(b) (4) Avia McClain-Stocker	26 Oct 2020 17:56:13
	(b) (4)	

US3052312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered '10:32'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:13

US3052312

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[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 10:32'	System	26 Oct 2020 17:56:13

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '25 Sep 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

[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)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '10:35'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:58:24

[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 10:35'	System	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[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)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'No (N)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:58:24

[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	26 Oct 2020 17:56:27

US3052312

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:15:47

US3052312

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'I'	System	26 Oct 2020 12:15:47

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:07', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e0aed08c-4c27-41c1-a43d-057ed339419b' User entered 'Yes (Y)'	System	25 Sep 2020 15:24:34
	System	25 Sep 2020 15:24:34

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:18', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e0aed08c-4c27-41c1-a43d-057ed339419b' User entered '98.3'	System	25 Sep 2020 15:24:34
	System	25 Sep 2020 15:24:34

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:23', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e0aed08c-4c27-41c1-a43d-057ed339419b' User entered 'No (N)'	System	25 Sep 2020 15:24:34
	System	25 Sep 2020 15:24:34

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:30', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e0aed08c-4c27-41c1-a43d-057ed339419b' User entered '25 Sep 2020 11:24'	System	25 Sep 2020 15:24:34
	System	25 Sep 2020 15:24:34

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 11:07'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 13:37'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:54:40', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'be9a7c47-0ee2-4bed-a595-15fa546e1bfa' User entered 'Yes (Y)'	System	25 Sep 2020 23:56:15
	System	25 Sep 2020 23:56:15

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:54:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'be9a7c47-0ee2-4bed-a595-15fa546e1bfa' User entered '97.3'	System	25 Sep 2020 23:56:15
	System	25 Sep 2020 23:56:15

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:54:52', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'be9a7c47-0ee2-4bed-a595-15fa546e1bfa' User entered 'No (N)'	System	25 Sep 2020 23:56:15
	System	25 Sep 2020 23:56:15

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:56:13', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'be9a7c47-0ee2-4bed-a595-15fa546e1bfa' User entered '25 Sep 2020 19:56'	System	25 Sep 2020 23:56:15
	System	25 Sep 2020 23:56:15

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 14:32'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 2'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:52:50', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd4844690-ab0c-4ad1-a4d9-d73bc904e600' User entered 'Yes (Y)'	System	26 Sep 2020 16:53:05
	System	26 Sep 2020 16:53:05

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:52:55', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd4844690-ab0c-4ad1-a4d9-d73bc904e600' User entered '97.5'	System	26 Sep 2020 16:53:05
	System	26 Sep 2020 16:53:05

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:52:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd4844690-ab0c-4ad1-a4d9-d73bc904e600'	System	26 Sep 2020 16:53:05
User entered 'No (N)'	System	26 Sep 2020 16:53:05

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:03', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd4844690-ab0c-4ad1-a4d9-d73bc904e600' User entered '26 Sep 2020 12:53'	System	26 Sep 2020 16:53:05
	System	26 Sep 2020 16:53:05

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 3'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:17:39', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5aad8b57-bab7-42e8-8a89-d023654c09f8'	System	28 Sep 2020 00:17:57
User entered 'Yes (Y)'	System	28 Sep 2020 00:17:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:17:43', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5aad8b57-bab7-42e8-8a89-d023654c09f8' User entered '98.0'	System	28 Sep 2020 00:17:57
	System	28 Sep 2020 00:17:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:17:47', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5aad8b57-bab7-42e8-8a89-d023654c09f8' User entered 'No (N)'	System	28 Sep 2020 00:17:57
	System	28 Sep 2020 00:17:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:17:52', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5aad8b57-bab7-42e8-8a89-d023654c09f8' User entered '27 Sep 2020 20:17'	System	28 Sep 2020 00:17:57
	System	28 Sep 2020 00:17:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 4'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:28:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4ee12ed8-5be3-4b6e-9a06-83c0442969ba' User entered 'Yes (Y)'	System	28 Sep 2020 21:29:09
	System	28 Sep 2020 21:29:09

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:02', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4ee12ed8-5be3-4b6e-9a06-83c0442969ba' User entered '95.8'	System	28 Sep 2020 21:29:09
	System	28 Sep 2020 21:29:09

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:04', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4ee12ed8-5be3-4b6e-9a06-83c0442969ba' User entered 'No (N)'	System	28 Sep 2020 21:29:09
	System	28 Sep 2020 21:29:09

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:07', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '4ee12ed8-5be3-4b6e-9a06-83c0442969ba' User entered '28 Sep 2020 17:29'	System	28 Sep 2020 21:29:09
	System	28 Sep 2020 21:29:09

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 5'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '426d1bd9-ab0b-4898-9543-cbfc301889f0' User entered 'Yes (Y)'	System	29 Sep 2020 23:38:25
	System	29 Sep 2020 23:38:25

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:19', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '426d1bd9-ab0b-4898-9543-cbfc301889f0' User entered '98.4'	System	29 Sep 2020 23:38:25
	System	29 Sep 2020 23:38:25

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '426d1bd9-ab0b-4898-9543-cbfc301889f0' User entered 'No (N)'	System	29 Sep 2020 23:38:25
	System	29 Sep 2020 23:38:25

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '426d1bd9-ab0b-4898-9543-cbfc301889f0' User entered '29 Sep 2020 19:38'	System	29 Sep 2020 23:38:25
	System	29 Sep 2020 23:38:25

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 6'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:25', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'af22e01b-08f6-44ea-a7e2-a07edd0adde1' User entered 'Yes (Y)'	System	01 Oct 2020 00:03:38
	System	01 Oct 2020 00:03:38

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:29', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'af22e01b-08f6-44ea-a7e2-a07edd0adde1' User entered '98.0'	System	01 Oct 2020 00:03:38
	System	01 Oct 2020 00:03:38

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:31', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'af22e01b-08f6-44ea-a7e2-a07edd0adde1' User entered 'No (N)'	System	01 Oct 2020 00:03:38
	System	01 Oct 2020 00:03:38

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'af22e01b-08f6-44ea-a7e2-a07edd0adde1' User entered '30 Sep 2020 20:03'	System	01 Oct 2020 00:03:38
	System	01 Oct 2020 00:03:38

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 7'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:19:43', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2643adbb-088e-4846-8c5c-affb4ad41561' User entered 'Yes (Y)'	System	02 Oct 2020 00:19:57
	System	02 Oct 2020 00:19:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:19:48', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2643adbb-088e-4846-8c5c-affb4ad41561' User entered '97.0'	System	02 Oct 2020 00:19:57
	System	02 Oct 2020 00:19:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:19:52', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2643adbb-088e-4846-8c5c-affb4ad41561' User entered 'No (N)'	System	02 Oct 2020 00:19:57
	System	02 Oct 2020 00:19:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:19:54', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2643adbb-088e-4846-8c5c-affb4ad41561' User entered '01 Oct 2020 20:19'	System	02 Oct 2020 00:19:57
	System	02 Oct 2020 00:19:57

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:35', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd3799e5-8ae8-49f5-9d84-e53249a0ea24'	System	25 Sep 2020 15:25:34
User entered 'None (1)'	System	25 Sep 2020 15:25:34

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:39', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd3799e5-8ae8-49f5-9d84-e53249a0ea24' User entered 'No (N)'	System	25 Sep 2020 15:25:34
	System	25 Sep 2020 15:25:34

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:43', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd3799e5-8ae8-49f5-9d84-e53249a0ea24' User entered 'No (N)'	System	25 Sep 2020 15:25:34
	System	25 Sep 2020 15:25:34

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:49', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd3799e5-8ae8-49f5-9d84-e53249a0ea24'	System	25 Sep 2020 15:25:34
User entered 'None (1)'	System	25 Sep 2020 15:25:34

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:24:51', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd3799e5-8ae8-49f5-9d84-e53249a0ea24' User entered '25 Sep 2020 11:24'	System	25 Sep 2020 15:25:34
	System	25 Sep 2020 15:25:34

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 11:07'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 13:37'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:56:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '7155a139-054c-4f00-9878-8189db3d1280'	System	25 Sep 2020 23:57:31
User entered 'None (1)'	System	25 Sep 2020 23:57:31

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:57:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '7155a139-054c-4f00-9878-8189db3d1280'	System	25 Sep 2020 23:57:31
User entered 'No (N)'	System	25 Sep 2020 23:57:31

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:57:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '7155a139-054c-4f00-9878-8189db3d1280' User entered 'No (N)'	System	25 Sep 2020 23:57:31
	System	25 Sep 2020 23:57:31

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:57:21', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '7155a139-054c-4f00-9878-8189db3d1280'	System	25 Sep 2020 23:57:31
User entered 'None (1)'	System	25 Sep 2020 23:57:31

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:57:25', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '7155a139-054c-4f00-9878-8189db3d1280'	System	25 Sep 2020 23:57:31
User entered '25 Sep 2020 19:57'	System	25 Sep 2020 23:57:31

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 14:32'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 2'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:11', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '80a638df-8340-4833-9cbf-f4137681f52d'	System	26 Sep 2020 16:53:37
User entered 'None (1)'	System	26 Sep 2020 16:53:37

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:21', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '80a638df-8340-4833-9cbf-f4137681f52d' User entered 'No (N)'	System	26 Sep 2020 16:53:37
	System	26 Sep 2020 16:53:37

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '80a638df-8340-4833-9cbf-f4137681f52d' User entered 'No (N)'	System	26 Sep 2020 16:53:37
	System	26 Sep 2020 16:53:37

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:30', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '80a638df-8340-4833-9cbf-f4137681f52d' User entered 'None (1)'	System	26 Sep 2020 16:53:37
	System	26 Sep 2020 16:53:37

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '80a638df-8340-4833-9cbf-f4137681f52d' User entered '26 Sep 2020 12:53'	System	26 Sep 2020 16:53:37
	System	26 Sep 2020 16:53:37

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 3'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:17:55', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '8c2a058c-caa7-4193-b8e1-fa38bebb78e9' User entered 'None (1)'	System	28 Sep 2020 00:18:08
	System	28 Sep 2020 00:18:08

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:17:59', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '8c2a058c-caa7-4193-b8e1-fa38bebb78e9' User entered 'No (N)'	System	28 Sep 2020 00:18:08
	System	28 Sep 2020 00:18:08

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:01', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '8c2a058c-caa7-4193-b8e1-fa38bebb78e9' User entered 'No (N)'	System	28 Sep 2020 00:18:08
	System	28 Sep 2020 00:18:08

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:04', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '8c2a058c-caa7-4193-b8e1-fa38bebb78e9' User entered 'None (1)'	System	28 Sep 2020 00:18:08
	System	28 Sep 2020 00:18:08

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:06', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '8c2a058c-caa7-4193-b8e1-fa38bebb78e9' User entered '27 Sep 2020 20:18'	System	28 Sep 2020 00:18:08
	System	28 Sep 2020 00:18:08

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 4'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:10', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'c8fbff39-4a87-47d2-a601-dd776ac08ffb' User entered 'None (1)'	System	28 Sep 2020 21:29:22
	System	28 Sep 2020 21:29:22

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:13', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'c8fbff39-4a87-47d2-a601-dd776ac08ffb' User entered 'No (N)'	System	28 Sep 2020 21:29:22
	System	28 Sep 2020 21:29:22

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'c8fbff39-4a87-47d2-a601-dd776ac08ffb' User entered 'No (N)'	System	28 Sep 2020 21:29:22
	System	28 Sep 2020 21:29:22

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:17', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'c8fbff39-4a87-47d2-a601-dd776ac08ffb' User entered 'None (1)'	System	28 Sep 2020 21:29:22
	System	28 Sep 2020 21:29:22

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:20', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'c8fbff39-4a87-47d2-a601-dd776ac08ffb' User entered '28 Sep 2020 17:29'	System	28 Sep 2020 21:29:22
	System	28 Sep 2020 21:29:22

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 5'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:28', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '236fee1e-ea5b-4328-8687-ade4efc1e2b5'	System	29 Sep 2020 23:38:40
User entered 'None (1)'	System	29 Sep 2020 23:38:40

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:30', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '236fee1e-ea5b-4328-8687-ade4efc1e2b5'	System	29 Sep 2020 23:38:40
User entered 'No (N)'	System	29 Sep 2020 23:38:40

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:32', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '236fee1e-ea5b-4328-8687-ade4efc1e2b5'	System	29 Sep 2020 23:38:40
User entered 'No (N)'	System	29 Sep 2020 23:38:40

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '236fee1e-ea5b-4328-8687-ade4efc1e2b5' User entered 'None (1)'	System	29 Sep 2020 23:38:40
	System	29 Sep 2020 23:38:40

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:38', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '236fee1e-ea5b-4328-8687-ade4efc1e2b5' User entered '29 Sep 2020 19:38'	System	29 Sep 2020 23:38:40
	System	29 Sep 2020 23:38:40

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 6'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:37', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '104ee269-2b7c-4ce3-8008-cafbdfbfe1ad'	System	01 Oct 2020 00:03:46
User entered 'None (1)'	System	01 Oct 2020 00:03:46

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:40', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '104ee269-2b7c-4ce3-8008-cafbdfbfe1ad' User entered 'No (N)'	System	01 Oct 2020 00:03:46
	System	01 Oct 2020 00:03:46

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:41', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '104ee269-2b7c-4ce3-8008-cafbdfbfe1ad' User entered 'No (N)'	System	01 Oct 2020 00:03:46
	System	01 Oct 2020 00:03:46

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:43', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '104ee269-2b7c-4ce3-8008-cafbdfbfe1ad'	System	01 Oct 2020 00:03:46
User entered 'None (1)'	System	01 Oct 2020 00:03:46

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:45', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '104ee269-2b7c-4ce3-8008-cafbdfbfe1ad'	System	01 Oct 2020 00:03:46
User entered '30 Sep 2020 20:03'	System	01 Oct 2020 00:03:46

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 7'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:19:57', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5b782ce3-d2e0-4937-b775-e953d9771e5c'	System	02 Oct 2020 00:20:09
User entered 'None (1)'	System	02 Oct 2020 00:20:09

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:01', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5b782ce3-d2e0-4937-b775-e953d9771e5c' User entered 'No (N)'	System	02 Oct 2020 00:20:09
	System	02 Oct 2020 00:20:09

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:03', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5b782ce3-d2e0-4937-b775-e953d9771e5c'	System	02 Oct 2020 00:20:09
User entered 'No (N)'	System	02 Oct 2020 00:20:09

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:04', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5b782ce3-d2e0-4937-b775-e953d9771e5c'	System	02 Oct 2020 00:20:09
User entered 'None (1)'	System	02 Oct 2020 00:20:09

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:07', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5b782ce3-d2e0-4937-b775-e953d9771e5c' User entered '01 Oct 2020 20:20'	System	02 Oct 2020 00:20:09
	System	02 Oct 2020 00:20:09

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:03', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6' User entered 'None (0)'	System	25 Sep 2020 15:25:37
	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:05', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6' User entered 'None (0)'	System	25 Sep 2020 15:25:37
	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6' User entered 'None (0)'	System	25 Sep 2020 15:25:37
	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:11', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6' User entered 'None (0)'	System	25 Sep 2020 15:25:37
	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:13', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6' User entered 'None (0)'	System	25 Sep 2020 15:25:37
	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6' User entered 'None (0)'	System	25 Sep 2020 15:25:37
	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:28', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6'	System	25 Sep 2020 15:25:37
User entered 'No (N)'	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T11:25:32', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bd2a02df-4854-4f38-9b76-7c14b72990c6' User entered '25 Sep 2020 11:25'	System	25 Sep 2020 15:25:37
	System	25 Sep 2020 15:25:37

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 11:07'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 13:37'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:57:57', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered 'None (0)'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:58:10', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered 'None (0)'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:58:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered 'None (0)'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:58:18', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered 'None (0)'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:58:30', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered 'None (0)'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:58:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered 'None (0)'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:58:37', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered 'No (N)'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-25T19:58:40', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e90c59ca-9d5a-432e-b53c-63e173299476' User entered '25 Sep 2020 19:58'	System	25 Sep 2020 23:58:41
	System	25 Sep 2020 23:58:41

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '25 Sep 2020 14:32'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 2'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:52', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce'	System	26 Sep 2020 16:54:26
User entered 'No interference with activity (1)'	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:53:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce'	System	26 Sep 2020 16:54:26
User entered 'No interference with activity (1)'	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:54:06', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce' User entered 'None (0)'	System	26 Sep 2020 16:54:26
	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:54:09', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce' User entered 'None (0)'	System	26 Sep 2020 16:54:26
	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:54:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce'	System	26 Sep 2020 16:54:26
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:54:17', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce' User entered 'None (0)'	System	26 Sep 2020 16:54:26
	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:54:19', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce'	System	26 Sep 2020 16:54:26
User entered 'No (N)'	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-26T12:54:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '78c88b93-fbd3-47d2-a6bd-576ddf16d5ce' User entered '26 Sep 2020 12:54'	System	26 Sep 2020 16:54:26
	System	26 Sep 2020 16:54:26

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 3'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:10', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153' User entered 'None (0)'	System	28 Sep 2020 00:18:29
	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153' User entered 'None (0)'	System	28 Sep 2020 00:18:29
	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:14', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153' User entered 'None (0)'	System	28 Sep 2020 00:18:29
	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153' User entered 'None (0)'	System	28 Sep 2020 00:18:29
	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:18', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153' User entered 'None (0)'	System	28 Sep 2020 00:18:29
	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:19', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153' User entered 'None (0)'	System	28 Sep 2020 00:18:29
	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153'	System	28 Sep 2020 00:18:29
User entered 'No (N)'	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-27T20:18:28', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9c2a0811-10ca-4ea8-80b0-2851b9384153'	System	28 Sep 2020 00:18:29
User entered '27 Sep 2020 20:18'	System	28 Sep 2020 00:18:29

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 4'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:25', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered 'None (0)'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:27', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered 'None (0)'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:29', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered 'None (0)'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:31', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered 'None (0)'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:33', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered 'None (0)'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:35', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered 'None (0)'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:38', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered 'No (N)'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-28T17:29:42', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc999955-d1b8-4dcd-b987-b36d463c7dd9' User entered '28 Sep 2020 17:29'	System	28 Sep 2020 21:29:45
	System	28 Sep 2020 21:29:45

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 5'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:42', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered 'None (0)'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:44', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered 'None (0)'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered 'None (0)'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:47', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered 'None (0)'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:49', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered 'None (0)'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:50', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered 'None (0)'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:54', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered 'No (N)'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-29T19:38:56', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'da4efc02-5917-4e50-b5c0-ed2ac0522f0d' User entered '29 Sep 2020 19:38'	System	29 Sep 2020 23:39:01
	System	29 Sep 2020 23:39:01

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 6'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:48', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered 'None (0)'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:50', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered 'None (0)'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:51', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered 'None (0)'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:53', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered 'None (0)'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:54', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered 'None (0)'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:56', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered 'None (0)'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:03:59', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered 'No (N)'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-09-30T20:04:01', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'bf5a6ae6-1fb2-494b-9d09-467d83ad9201' User entered '30 Sep 2020 20:04'	System	01 Oct 2020 00:04:05
	System	01 Oct 2020 00:04:05

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	25 Sep 2020 15:23:48
User entered 'Day 7'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:10', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered 'None (0)'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered 'None (0)'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:13', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered 'None (0)'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:14', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered 'None (0)'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered 'None (0)'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:17', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered 'None (0)'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:20', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered 'No (N)'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-01T20:20:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b638d06a-ebc9-4ff5-911a-5e0cc86b573b' User entered '01 Oct 2020 20:20'	System	02 Oct 2020 00:20:27
	System	02 Oct 2020 00:20:27

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 15:23:48

US3052312

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:58:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 15:23:48

US3052312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:52:21

US3052312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '5 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:52:21

US3052312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:52:21

US3052312

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'left message'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:52:21

US3052312

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:16:13

US3052312

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'I'	System	26 Oct 2020 12:16:13

US3052312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	26 Oct 2020 17:53:04
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	26 Oct 2020 17:52:46
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 17:52:46

US3052312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	26 Oct 2020 17:53:25
User entered '9 Oct 2020' reason for change: Data Entry Error	System	26 Oct 2020 17:53:25
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Avia McClain-Stocker	26 Oct 2020 17:53:25
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	System	26 Oct 2020 17:53:04
	Avia McClain-Stocker	26 Oct 2020 17:53:04
	(b) (4)	
	Avia McClain-Stocker	26 Oct 2020 17:52:46
	(b) (4)	

US3052312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:52:46

US3052312

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:52:46

US3052312

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:16:18

US3052312

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'I'	System	26 Oct 2020 12:16:18

US3052312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:53:43

US3052312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '16 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:53:43

US3052312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:53:43

US3052312

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 17:53:43

US3052312

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:16:23

US3052312

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'I'	System	26 Oct 2020 12:16:23

US3052312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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)	08 Apr 2021 20:43:42
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "updated in preclarus as correct date" Still there is no collection date got updated in the Preclarus for the sample with preclarus Requisition kit id 1F604410086 for illness visit day 1 for in PPD central lab. Please review the Preclarus and update the missing Date of collection' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 07:38:44
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "updated in preclarus as correct date" Still there is no collection date got updated in the Preclarus for the sample with preclarus Requisition kit id 1F654640190 for illness visit day 1 for in PPD central lab. Please review the Preclarus and update the missing Date of collection' canceled (Site from DM).		05 Apr 2021 07:38:34
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "updated in preclarus as correct date" Still there is no collection date got updated in the Preclarus for the sample with preclarus Requisition kit id 1F654640190 for illness visit day 1 for in PPD central lab. Please review the Preclarus and update the missing Date of collection' (Site from DM).		29 Mar 2021 11:35:26
User closed query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample under illness visit with Preclarus Requisition kit id 1F654640190 with Missing date of collection. Please review the Preclarus and update the date of collection in Preclarus ' (Site from DM).		29 Mar 2021 11:35:26
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Re-Query: As per the response "updated in preclarus as correct date" Still there is no collection date got updated in the Preclarus for the sample with preclarus Requisition kit id 1F604410086 for illness visit day 1 for in PPD central lab. Please review the Preclarus and update the missing Date of collection' (Site from DM).		29 Mar 2021 11:34:51

US3052312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample under illness visit with Preclarus Requisition kit id 1F604410086 with Missing date of collection. Please review the Preclarus and update the date of collection in Preclarus ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:34:51
Query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample under illness visit with Preclarus Requisition kit id 1F654640190 with Missing date of collection. Please review the Preclarus and update the date of collection in Preclarus ' answered with 'updated in preclarus as correct date' (Site from DM).		24 Mar 2021 14:48:11
Query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample under illness visit with Preclarus Requisition kit id 1F604410086 with Missing date of collection. Please review the Preclarus and update the date of collection in Preclarus ' answered with 'updated in preclarus as correct date' (Site from DM).		24 Mar 2021 14:48:08
User opened query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample under illness visit with Preclarus Requisition kit id 1F654640190 with Missing date of collection. Please review the Preclarus and update the date of collection in Preclarus ' (Site from DM).		24 Mar 2021 07:01:24
User opened query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample under illness visit with Preclarus Requisition kit id 1F604410086 with Missing date of collection. Please review the Preclarus and update the date of collection in Preclarus ' (Site from DM).		24 Mar 2021 07:01:07
User closed query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample as Illness Day1 visit with Missing date of collection and it is missing EDC. Please review Preclarus and update the missing Date of collection. Also record the data in EDC and confirm in the response.' (Site from DM).		24 Mar 2021 06:56:01

US3052312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample as Illness Day1 visit with Missing date of collection and it is missing EDC. Please review Preclarus and update the missing Date of collection. Also record the data in EDC and confirm in the response.' answered with 'Reviewed and updated' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:48:27
User opened query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample as Illness Day1 visit with Missing date of collection and it is missing EDC. Please review Preclarus and update the missing Date of collection. Also record the data in EDC and confirm in the response.' (Site from DM).		26 Feb 2021 06:39:41
Query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample as Illness Day1 visit with Missing date of collection and it is missing EDC. Please review Preclarus and update the missing Date of collection. Also record the data in EDC and confirm in the response' canceled (Site from DM).		26 Feb 2021 06:37:35
User opened query 'Per GCL Lab Recon: SARS-COV2: PPD has SARS-COV2 sample as Illness Day1 visit with Missing date of collection and it is missing EDC. Please review Preclarus and update the missing Date of collection. Also record the data in EDC and confirm in the response' (Site from DM).		26 Feb 2021 06:37:18
User entered 'Yes (Y)'	Avia McClain-Stocker (b) (4)	26 Oct 2020 12:16:34

US3052312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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)	08 Apr 2021 20:43:42
User entered '23 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:16:34

US3052312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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)	08 Apr 2021 20:43:42
User entered 'Clinic (Clinic)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:16:34

US3052312

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'VISIT3'	System	26 Oct 2020 12:16:34

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

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 16:53:18
User entered '23 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

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 16:53:18
User entered '14:23'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 '23 Oct 2020 14:23'	System	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered '98.6' F	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered 'Oral (Oral)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered empty.	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered '83'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered '14'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered '110'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered '74'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 12:17:03

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09

US3052312

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09

US3052312

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[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 16:53:18
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:09

US3052312

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

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 16:53:18
User entered '23 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:09

US3052312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:22

US3052312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '23 Oct 2020'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:22

US3052312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '15:58'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:22

US3052312

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered '23 Oct 2020 15:58'	System	26 Oct 2020 12:17:22

US3052312

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	26 Oct 2020 12:17:25

US3052312

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'I'	System	26 Oct 2020 12:17:25

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 64'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-28T07:01:14', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '015d7575-5532-4c29-a8e5-7dd021f3645c'	System	28 Oct 2020 11:01:49
User entered 'No (N)'	System	28 Oct 2020 11:01:49

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-28T07:01:42', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '015d7575-5532-4c29-a8e5-7dd021f3645c'	System	28 Oct 2020 11:01:49
User entered 'No (N)'	System	28 Oct 2020 11:01:49

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-10-28T07:01:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '015d7575-5532-4c29-a8e5-7dd021f3645c' User entered '28 Oct 2020 07:01:46'	System	28 Oct 2020 11:01:49
	System	28 Oct 2020 11:01:49

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 71'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-04T07:41:49', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '767d3757-5050-4de1-a6ae-baaa226808b4'	System	04 Nov 2020 12:42:05
User entered 'No (N)'	System	04 Nov 2020 12:42:05

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-04T07:41:56', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '767d3757-5050-4de1-a6ae-baaa226808b4'	System	04 Nov 2020 12:42:05
User entered 'No (N)'	System	04 Nov 2020 12:42:05

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-04T07:42:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '767d3757-5050-4de1-a6ae-baaa226808b4' User entered '04 Nov 2020 07:42:00'	System	04 Nov 2020 12:42:05
	System	04 Nov 2020 12:42:05

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered 'Day 78'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-11T08:00:09', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b8623e68-bbd3-4138-a4a3-1c1f9cdc76f4'	System	11 Nov 2020 13:00:18
User entered 'No (N)'	System	11 Nov 2020 13:00:18

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-11T08:00:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b8623e68-bbd3-4138-a4a3-1c1f9cdc76f4'	System	11 Nov 2020 13:00:18
User entered 'No (N)'	System	11 Nov 2020 13:00:18

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-11T08:00:16', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b8623e68-bbd3-4138-a4a3-1c1f9cdc76f4' User entered '11 Nov 2020 08:00:16'	System	11 Nov 2020 13:00:18
	System	11 Nov 2020 13:00:18

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 19:58:11

US3052312

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:23:22
Data entry locked.	System	28 Aug 2020 19:58:11
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 19:58:11

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:11', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered 'Yes (Y)'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:18', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered 'Yes (Y)'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:28', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '1'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '1'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795' User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '1'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '1'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '1'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '1'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795' User entered '1'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:17:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered '0'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:18:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:18:20', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered 'Yes (Y)'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:18:23', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795'	System	24 Nov 2020 21:18:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-11-24T16:18:28', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '361488de-9e1d-436c-a405-57007c1ea795' User entered '24 Nov 2020 16:18:28'	System	24 Nov 2020 21:18:38
	System	24 Nov 2020 21:18:38

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:12:31', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered 'Yes (Y)'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:12:48', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered 'Yes (Y)'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:13:02', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:18:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered 'Yes (Y)'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '1'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '1'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '1'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '1'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '1'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '1'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:12', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '0'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:16', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:25', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered 'No (N)'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-03T15:19:31', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f34a9079-398a-4b87-821b-0884f8f21480'	System	03 Dec 2020 20:19:41
User entered '03 Dec 2020 15:19:31'	System	03 Dec 2020 20:19:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-06T12:12:20', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '0eb4fe2f-f77d-4e23-8186-6d9489fbe9a5' User entered 'No (N)'	System	06 Dec 2020 17:12:31
	System	06 Dec 2020 17:12:31

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-06T12:12:24', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '0eb4fe2f-f77d-4e23-8186-6d9489fbe9a5'	System	06 Dec 2020 17:12:31
User entered 'No (N)'	System	06 Dec 2020 17:12:31

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-06T12:12:27', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '0eb4fe2f-f77d-4e23-8186-6d9489fbe9a5' User entered '06 Dec 2020 12:12:27'	System	06 Dec 2020 17:12:31
	System	06 Dec 2020 17:12:31

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-15T19:08:39', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '0fb3cd67-cc5e-499b-b008-c148db95fa14'	System	16 Dec 2020 00:08:54
User entered 'No (N)'	System	16 Dec 2020 00:08:54

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-15T19:08:49', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '0fb3cd67-cc5e-499b-b008-c148db95fa14' User entered 'No (N)'	System	16 Dec 2020 00:08:54

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-15T19:08:53', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '0fb3cd67-cc5e-499b-b008-c148db95fa14' User entered '15 Dec 2020 19:08:53'	System	16 Dec 2020 00:08:54
	System	16 Dec 2020 00:08:54

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-20T13:44:16', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f377e20e-be75-4f52-9098-8b804d347e45'	System	20 Dec 2020 18:44:30
User entered 'No (N)'	System	20 Dec 2020 18:44:30

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-20T13:44:23', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f377e20e-be75-4f52-9098-8b804d347e45'	System	20 Dec 2020 18:44:30
User entered 'No (N)'	System	20 Dec 2020 18:44:30

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-20T13:44:27', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f377e20e-be75-4f52-9098-8b804d347e45'	System	20 Dec 2020 18:44:30
User entered '20 Dec 2020 13:44:27'	System	20 Dec 2020 18:44:30

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-28T20:56:29', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f304e9bd-5d33-4278-90de-417678a08f95'	System	29 Dec 2020 01:56:41
User entered 'No (N)'	System	29 Dec 2020 01:56:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-28T20:56:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f304e9bd-5d33-4278-90de-417678a08f95'	System	29 Dec 2020 01:56:41
User entered 'No (N)'	System	29 Dec 2020 01:56:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2020-12-28T20:56:37', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f304e9bd-5d33-4278-90de-417678a08f95' User entered '28 Dec 2020 20:56:37'	System	29 Dec 2020 01:56:41
	System	29 Dec 2020 01:56:41

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-04T19:35:44', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'acfecbf-28bb-494e-94ed-93383cb6039c'	System	05 Jan 2021 00:36:12
User entered 'No (N)'	System	05 Jan 2021 00:36:12

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-04T19:36:05', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'acfeccbf-28bb-494e-94ed-93383cb6039c'	System	05 Jan 2021 00:36:12
User entered 'No (N)'	System	05 Jan 2021 00:36:12

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-04T19:36:08', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'acfeccbf-28bb-494e-94ed-93383cb6039c' User entered '04 Jan 2021 19:36:08'	System	05 Jan 2021 00:36:12
	System	05 Jan 2021 00:36:12

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-10T19:43:07', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '73e12347-9ca6-4a60-920e-a929db53bebe' User entered 'No (N)'	System	11 Jan 2021 00:43:24
	System	11 Jan 2021 00:43:24

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-10T19:43:18', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '73e12347-9ca6-4a60-920e-a929db53bebe' User entered 'No (N)'	System	11 Jan 2021 00:43:24
	System	11 Jan 2021 00:43:24

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-10T19:43:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '73e12347-9ca6-4a60-920e-a929db53bebe' User entered '10 Jan 2021 19:43:22'	System	11 Jan 2021 00:43:24
	System	11 Jan 2021 00:43:24

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-18T00:00:22', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1f20986d-6248-47d9-9747-a4dce0351871'	System	18 Jan 2021 05:00:39
User entered 'No (N)'	System	18 Jan 2021 05:00:39

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-18T00:00:27', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1f20986d-6248-47d9-9747-a4dce0351871'	System	18 Jan 2021 05:00:39
User entered 'No (N)'	System	18 Jan 2021 05:00:39

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-18T00:00:31', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1f20986d-6248-47d9-9747-a4dce0351871' User entered '18 Jan 2021 00:00:31'	System	18 Jan 2021 05:00:39
	System	18 Jan 2021 05:00:39

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-24T09:50:10', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '20a21208-0698-46ed-adcd-2aea5513e434'	System	24 Jan 2021 14:50:23
User entered 'No (N)'	System	24 Jan 2021 14:50:23

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-24T09:50:14', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '20a21208-0698-46ed-adcd-2aea5513e434'	System	24 Jan 2021 14:50:23
User entered 'No (N)'	System	24 Jan 2021 14:50:23

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-01-24T09:50:17', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '20a21208-0698-46ed-adcd-2aea5513e434' User entered '24 Jan 2021 09:50:17'	System	24 Jan 2021 14:50:23
	System	24 Jan 2021 14:50:23

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-01T17:30:09', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2d47e744-5ef5-4042-8843-e52818c6cea7' User entered 'Yes (Y)'	System	01 Feb 2021 22:31:01
	System	01 Feb 2021 22:31:01

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-01T17:30:15', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2d47e744-5ef5-4042-8843-e52818c6cea7'	System	01 Feb 2021 22:31:01
User entered 'No (N)'	System	01 Feb 2021 22:31:01

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-01T17:30:26', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2d47e744-5ef5-4042-8843-e52818c6cea7' User entered 'No (N)'	System	01 Feb 2021 22:31:01

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-01T17:30:34', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2d47e744-5ef5-4042-8843-e52818c6cea7' User entered 'Yes (Y)'	System	01 Feb 2021 22:31:01
	System	01 Feb 2021 22:31:01

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-01T17:30:46', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2d47e744-5ef5-4042-8843-e52818c6cea7'	System	01 Feb 2021 22:31:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 22:31:01

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-01T17:30:51', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2d47e744-5ef5-4042-8843-e52818c6cea7' User entered '01 Feb 2021 17:30:51'	System	01 Feb 2021 22:31:01
	System	01 Feb 2021 22:31:01

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-08T20:30:54', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd7f6a0bb-1533-467a-a48c-8bb758549a19' User entered 'No (N)'	System	09 Feb 2021 01:31:08
	System	09 Feb 2021 01:31:08

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-08T20:30:59', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd7f6a0bb-1533-467a-a48c-8bb758549a19'	System	09 Feb 2021 01:31:08
User entered 'No (N)'	System	09 Feb 2021 01:31:08

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-08T20:31:02', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd7f6a0bb-1533-467a-a48c-8bb758549a19' User entered '08 Feb 2021 20:31:02'	System	09 Feb 2021 01:31:08
	System	09 Feb 2021 01:31:08

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-14T18:46:41', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b3fc2d36-cbcb-481d-8104-dbaff6303277'	System	14 Feb 2021 23:46:51
User entered 'No (N)'	System	14 Feb 2021 23:46:51

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-14T18:46:45', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b3fc2d36-cbcb-481d-8104-dbaff6303277'	System	14 Feb 2021 23:46:51
User entered 'No (N)'	System	14 Feb 2021 23:46:51

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-14T18:46:49', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'b3fc2d36-cbcb-481d-8104-dbaff6303277'	System	14 Feb 2021 23:46:51
User entered '14 Feb 2021 18:46:49'	System	14 Feb 2021 23:46:51

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-21T22:11:54', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9cea9820-2bc3-4131-9eab-b34e28c06e58'	System	22 Feb 2021 03:12:49
User entered 'Yes (Y)'	System	22 Feb 2021 03:12:49

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-21T22:11:58', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9cea9820-2bc3-4131-9eab-b34e28c06e58' User entered 'No (N)'	System	22 Feb 2021 03:12:49
	System	22 Feb 2021 03:12:49

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-21T22:12:04', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9cea9820-2bc3-4131-9eab-b34e28c06e58' User entered 'No (N)'	System	22 Feb 2021 03:12:49
	System	22 Feb 2021 03:12:49

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-21T22:12:19', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9cea9820-2bc3-4131-9eab-b34e28c06e58' User entered 'Yes (Y)'	System	22 Feb 2021 03:12:49
	System	22 Feb 2021 03:12:49

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-21T22:12:29', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9cea9820-2bc3-4131-9eab-b34e28c06e58'	System	22 Feb 2021 03:12:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Feb 2021 03:12:49

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-21T22:12:40', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '9cea9820-2bc3-4131-9eab-b34e28c06e58' User entered '21 Feb 2021 22:12:40'	System	22 Feb 2021 03:12:49
	System	22 Feb 2021 03:12:49

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-28T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '3142e817-ae65-477d-97f0-594fd2256816' User entered 'No (N)'	System	28 Feb 2021 05:04:28
	System	28 Feb 2021 05:04:28

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-28T00:02:36-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '3142e817-ae65-477d-97f0-594fd2256816' User entered 'No (N)'	System	28 Feb 2021 05:04:28
	System	28 Feb 2021 05:04:28

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-28T00:02:39-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '3142e817-ae65-477d-97f0-594fd2256816' User entered '28 Feb 2021 05:02:39'	System	28 Feb 2021 05:04:28
	System	28 Feb 2021 05:04:28

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-07T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1ecd3647-c8e2-4cc3-8e64-4f865e31edbf'	System	07 Mar 2021 05:04:43
User entered 'No (N)'	System	07 Mar 2021 05:04:43

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-07T00:02:40-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1ecd3647-c8e2-4cc3-8e64-4f865e31edbf'	System	07 Mar 2021 05:04:43
User entered 'No (N)'	System	07 Mar 2021 05:04:43

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-07T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '1ecd3647-c8e2-4cc3-8e64-4f865e31edbf'	System	07 Mar 2021 05:04:43
User entered '07 Mar 2021 00:02:45'	System	07 Mar 2021 05:04:43

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-14T13:18:06-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2038c40c-4bf2-42cc-8e13-848805c4a8f6'	System	14 Mar 2021 17:18:23
User entered 'No (N)'	System	14 Mar 2021 17:18:23

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-14T13:18:17-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2038c40c-4bf2-42cc-8e13-848805c4a8f6'	System	14 Mar 2021 17:18:23
User entered 'No (N)'	System	14 Mar 2021 17:18:23

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-14T13:18:20-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '2038c40c-4bf2-42cc-8e13-848805c4a8f6'	System	14 Mar 2021 17:18:23
User entered '14 Mar 2021 13:18:20'	System	14 Mar 2021 17:18:23

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-21T18:19:52-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc8ad5c1-91c0-4143-a47b-40e3443b5790'	System	21 Mar 2021 22:19:59
User entered 'No (N)'	System	21 Mar 2021 22:19:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-21T18:19:54-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc8ad5c1-91c0-4143-a47b-40e3443b5790'	System	21 Mar 2021 22:19:59
User entered 'No (N)'	System	21 Mar 2021 22:19:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-21T18:19:57-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'fc8ad5c1-91c0-4143-a47b-40e3443b5790' User entered '21 Mar 2021 18:19:57'	System	21 Mar 2021 22:19:59
	System	21 Mar 2021 22:19:59

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-30T12:00:50-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'eed1342c-b338-4e41-83de-b0d1465a441f' User entered 'No (N)'	System	30 Mar 2021 16:03:13
	System	30 Mar 2021 16:03:13

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-30T12:00:56-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'eed1342c-b338-4e41-83de-b0d1465a441f'	System	30 Mar 2021 16:03:13
User entered 'No (N)'	System	30 Mar 2021 16:03:13

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-03-30T12:01:04-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'eed1342c-b338-4e41-83de-b0d1465a441f' User entered '30 Mar 2021 12:01:04'	System	30 Mar 2021 16:03:13
	System	30 Mar 2021 16:03:13

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-04T21:09:35-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '194f582b-2c03-45fa-9e72-735cc43aac6b' User entered 'No (N)'	System	05 Apr 2021 01:12:00
	System	05 Apr 2021 01:12:00

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-04T21:09:38-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '194f582b-2c03-45fa-9e72-735cc43aac6b'	System	05 Apr 2021 01:12:00
User entered 'No (N)'	System	05 Apr 2021 01:12:00

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-04T21:09:47-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '194f582b-2c03-45fa-9e72-735cc43aac6b' User entered '04 Apr 2021 21:09:47'	System	05 Apr 2021 01:12:00
	System	05 Apr 2021 01:12:00

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-12T21:42:51-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e6097a58-144f-4f0e-8132-bfd08a0c1728'	System	13 Apr 2021 01:44:24
User entered 'No (N)'	System	13 Apr 2021 01:44:24

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-12T21:42:54-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e6097a58-144f-4f0e-8132-bfd08a0c1728'	System	13 Apr 2021 01:44:24
User entered 'No (N)'	System	13 Apr 2021 01:44:24

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-12T21:42:58-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'e6097a58-144f-4f0e-8132-bfd08a0c1728'	System	13 Apr 2021 01:44:24
User entered '12 Apr 2021 21:42:58'	System	13 Apr 2021 01:44:24

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-21T01:21:39-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f66f1c5e-55a9-42f4-a44f-9b389a508d5c'	System	21 Apr 2021 05:22:03
User entered 'No (N)'	System	21 Apr 2021 05:22:03

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-21T01:21:44-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f66f1c5e-55a9-42f4-a44f-9b389a508d5c'	System	21 Apr 2021 05:22:03
User entered 'Yes (Y)'	System	21 Apr 2021 05:22:03

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-21T01:21:46-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f66f1c5e-55a9-42f4-a44f-9b389a508d5c'	System	21 Apr 2021 05:22:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Apr 2021 05:22:03

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-21T01:21:51-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'f66f1c5e-55a9-42f4-a44f-9b389a508d5c' User entered '21 Apr 2021 01:21:51'	System	21 Apr 2021 05:22:03
	System	21 Apr 2021 05:22:03

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-26T12:42:06-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd84c8f8c-7314-4b71-9e18-e2ecbf221db0'	System	26 Apr 2021 16:42:16
User entered 'No (N)'	System	26 Apr 2021 16:42:16

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-26T12:42:09-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd84c8f8c-7314-4b71-9e18-e2ecbf221db0'	System	26 Apr 2021 16:42:16
User entered 'No (N)'	System	26 Apr 2021 16:42:16

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-04-26T12:42:11-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: 'd84c8f8c-7314-4b71-9e18-e2ecbf221db0'	System	26 Apr 2021 16:42:16
User entered '26 Apr 2021 12:42:11'	System	26 Apr 2021 16:42:16

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-05-02T09:17:25-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5214a65a-e167-4468-8864-a031ab21c400'	System	02 May 2021 13:17:34
User entered 'No (N)'	System	02 May 2021 13:17:34

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

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 (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-05-02T09:17:28-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5214a65a-e167-4468-8864-a031ab21c400'	System	02 May 2021 13:17:34
User entered 'No (N)'	System	02 May 2021 13:17:34

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-05-02T09:17:32-04:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '5214a65a-e167-4468-8864-a031ab21c400'	System	02 May 2021 13:17:34
User entered '02 May 2021 09:17:32'	System	02 May 2021 13:17:34

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:42:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:42:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:42:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:42:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:42:44

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:42:44

US3052312

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:58:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:42:44
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:42:44

US3052312

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:58:24

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)	24 Apr 2021 09:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-28T00:02:26-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '45bcb89a-3700-4042-91f3-26ace99035c0'	System	28 Feb 2021 05:04:19
User entered 'No (N)'	System	28 Feb 2021 05:04:19

US3052312

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:58:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:16:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3ECE1D6F-3882-4EC3-9746-600586B87113)', Time: '2021-02-28T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3052312)', ODM File OID: '45bcb89a-3700-4042-91f3-26ace99035c0' User entered '28 Feb 2021 05:02:30'	System	28 Feb 2021 05:04:19
	System	28 Feb 2021 05:04:19

US3052312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:55:57

US3052312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

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 16:53:08
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:55:57

US3052312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:55:57

US3052312

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:55:57

US3052312

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[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 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	04 Jan 2021 01:19:33
	(b) (4)	

US3052312

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:09
User entered 'I'	System	04 Jan 2021 01:19:33

US3052312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker (b) (4)	04 Jan 2021 01:20:03

US3052312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '22 Dec 2020'	(b) (4) Avia McClain-Stocker	04 Jan 2021 01:20:03
	(b) (4)	

US3052312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Avia McClain-Stocker (b) (4)	04 Jan 2021 01:20:03

US3052312

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) Avia McClain-Stocker	04 Jan 2021 01:20:03
	(b) (4)	

US3052312

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) Avia McClain-Stocker	04 Jan 2021 01:20:07
	(b) (4)	

US3052312

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User entered 'I'	System	04 Jan 2021 01:20:07

US3052312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:17:08

US3052312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
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 07:37:51
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'VERIFIED DATE OF CALL' (Site from System).	(b) (4), (b) (6)	14 Feb 2021 02:17:17
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 02:17:08
User entered '05 Feb 2021'	(b) (4), (b) (6)	14 Feb 2021 02:17:08

US3052312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Feb 2021 02:17:08

US3052312

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4), (b) (6)	14 Feb 2021 02:17:08

US3052312

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:22:57

US3052312

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:32:00
User entered 'I'	System	25 Feb 2021 18:22:57

US3052312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:45:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:23:29

US3052312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:45:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:23:29

US3052312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:45:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:23:29

US3052312

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:45:17
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Left voicemail'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:23:29

US3052312

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:45:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:46:04

US3052312

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:45:17
User entered 'I'	System	22 Mar 2021 14:46:04

US3052312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:41:08
Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' answered with 'vital signs are completed for both' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:37:30
User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).		30 Mar 2021 13:41:23
User entered 'Yes (Y)'		22 Mar 2021 14:46:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:46:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:46:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered 'VISIT4'	System	22 Mar 2021 14:46:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '14:21'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered '19 Mar 2021 14:21'	System	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '85'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered 'bpm'	System	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '17'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered 'breaths/min'	System	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '116'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered 'mmHg'	System	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '73'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered 'mmHg'	System	30 Mar 2021 19:40:40

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17

US3052312

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17

US3052312

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:46:52

US3052312

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:46:52

US3052312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:47:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:47:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '15:11'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:47:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered '19 Mar 2021 15:11'	System	22 Mar 2021 14:47:38

US3052312

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:40:46

US3052312

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:35:17
User entered 'I'	System	30 Mar 2021 19:40:46

US3052312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:22:56

US3052312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:22
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:22:56

US3052312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:22:56

US3052312

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:22
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 17:22:56

US3052312

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:22
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:23:01

US3052312

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 17:23:01

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:19
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:56:21

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:19
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '14:35'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:56:21

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:19
User entered '2 Feb 2021 14:35'	System	16 Apr 2021 12:56:21

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:19
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:56:21

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:19
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:56:21

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:08

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

US3052312

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:59:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 13:03:34

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Form: Symptom Log (3)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

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Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

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Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:34

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:12

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '30 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:06:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Form: Symptom Log (6)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:04

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '1 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 13:11:11

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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Form: Symptom Log (7)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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Form: Symptom Log (7)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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Form: Symptom Log (7)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:11:11

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '99'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:31:57

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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Form: Symptom Log (8)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

US3052312

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:31:57

US3052312

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '5 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:42:30

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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Folder: Covid-19 Assessment 02 Feb 2021

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:42:30

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '6 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:44:06

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Form: Symptom Log (10)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Form: Symptom Log (10)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Form: Symptom Log (10)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Form: Symptom Log (10)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Form: Symptom Log (10)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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Folder: Covid-19 Assessment 02 Feb 2021

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:44:06

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

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Form: Symptom Log (11)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '7 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:46:45

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '99'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:48:05

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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Form: Symptom Log (12)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

US3052312

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Form: Symptom Log (12)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:48:05

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

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Form: Symptom Log (13)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered empty.	System	16 Apr 2021 13:49:06

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

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Form: Symptom Log (13)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

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Form: Symptom Log (13)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

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Form: Symptom Log (13)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

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Form: Symptom Log (13)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

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Form: Symptom Log (13)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:06

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32
User entered 'Day 15 (Day 15)'		16 Apr 2021 13:50:32

US3052312

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

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Form: Symptom Log (14)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

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Form: Symptom Log (14)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

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Form: Symptom Log (14)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (14)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:50:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Form: Symptom Log (15)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:52:32

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Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Form: Symptom Log (15)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (15)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:52:32

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 18 (Day 18)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (16)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:53:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 19 (Day 19)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (17)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:56:03

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 20 (Day 20)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '14 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

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Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (18)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:57:42

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 21 (Day 21)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (19)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:59:10

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Day 22 (Day 22)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Generated On: 09 Jun 2021 14:58:24

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '100'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User entered '%'	System	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Form: Symptom Log (20)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Form: Symptom Log (20)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

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Folder: Covid-19 Assessment 02 Feb 2021

Form: Symptom Log (20)

Generated On: 09 Jun 2021 14:58:24

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:26
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:01:15

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[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)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 14:58:24

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:32
User entered '0'	System	16 Apr 2021 14:04:47

US3052312

Folder: Covid-19 Assessment 02 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:58:24

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:48:39
User signature succeeded.	Yaa Oppong (b) (4)	23 Apr 2021 13:52:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 13:37:11
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:27:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:27:28
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'No (N)'	(b) (4)	16 Apr 2021 14:04:56
	(b) (4), (b) (6)	

US3052312

Folder: Covid-19 Assessment 04 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:38
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Apr 2021 06:46:08
Query 'Data is required. Please complete.' answered with 'made in error new covid assessment wont allow me to delete it.' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 13:37:33
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 13:36:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Apr 2021 13:36:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:36:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Apr 2021 13:36:07
User entered '04 ' (non-conformant).	(b) (4), (b) (6)	22 Apr 2021 13:36:07
User entered '04 Feb 2021'		22 Apr 2021 13:31:06

US3052312

Folder: Covid-19 Assessment 04 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:38
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Apr 2021 06:46:10
Query 'Data is required. Please complete.' answered with 'made in error new covid assessment wont allow me to delete it.' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 13:37:35
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 13:36:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:36:07
User entered '16:00'		22 Apr 2021 13:31:06

US3052312

Folder: Covid-19 Assessment 04 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:38
User entered empty.	System	22 Apr 2021 13:36:07
User entered '04 Feb 2021 16:00'	System	22 Apr 2021 13:31:06

US3052312

Folder: Covid-19 Assessment 04 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:38
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Apr 2021 06:46:13
Query 'Data is required. Please complete.' answered with 'made in error new covid assessment wont allow me to delete it.' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 13:37:38
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 13:36:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:36:07
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'		22 Apr 2021 13:31:06

US3052312

Folder: Covid-19 Assessment 04 Feb 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:58:24

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:56:38
User signature succeeded.	Yaa Oppong (b) (4)	26 Apr 2021 20:36:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Apr 2021 06:46:15
Query 'Data is required. Please complete.' answered with 'made in error new covid assessment wont allow me to delete it.' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 13:37:42
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 13:36:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 13:36:07
User entered 'Yes (Y)' reason for change: Data Entry Error		22 Apr 2021 13:31:57
User entered 'No (N)'		22 Apr 2021 13:31:06

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:58:24

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: sample dated 06FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:28:41
Query 'Per GCL LAB reconciliation: Saliva: sample dated 06FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' answered with '1F604410086, EMAILED REQ TO PPD' (Site from DM).		06 Apr 2021 12:02:12
User opened query 'Per GCL LAB reconciliation: Saliva: sample dated 06FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' (Site from DM).		05 Apr 2021 11:24:58
User accepted default value 'Day 3 (Day 3)'		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:58:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 06FEB2021 is reported for Day 3 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 05:09:57
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
Query 'Per GCL Lab Recon: Saliva: Sample dated 06FEB2021 is reported for Day 3 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' answered with 'corrected' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:51:59
User entered '6 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 12:50:48
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 06FEB2021 is reported for Day 3 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).		14 Apr 2021 07:40:35
User entered '4 Feb 2021' reason for change: Data Entry Error		06 Apr 2021 12:02:22
User entered '6 Feb 2021'		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:58:24

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: sample dated 08FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:28:45
Query 'Per GCL LAB reconciliation: Saliva: sample dated 08FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' answered with '1F604410086, REQ EMAILED TO PPD' (Site from DM).		06 Apr 2021 12:03:02
User opened query 'Per GCL LAB reconciliation: Saliva: sample dated 08FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' (Site from DM).		05 Apr 2021 11:25:13
User accepted default value 'Day 5 (Day 5)'		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:58:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 08FEB2021 is reported for Day 5 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 05:10:16
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
Query 'Per GCL Lab Recon: Saliva: Sample dated 08FEB2021 is reported for Day 5 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' answered with 'corrected' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:52:47
User entered '8 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 12:52:38
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 08FEB2021 is reported for Day 5 under Illness visit in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal via DCF to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).		14 Apr 2021 07:40:55
User entered '4 Feb 2021' reason for change: Data Entry Error		06 Apr 2021 12:03:04
User entered '8 Feb 2021'		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:58:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:58:24

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 10feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).	(b) (4)	12 Apr 2021 12:22:45
Query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 10feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' answered with 'ppd is showing as received.	(b) (4), (b) (6)	09 Apr 2021 19:51:52
accession # 1F604573427 ' (Site from DM).		
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 10feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).		08 Apr 2021 08:09:54
User closed query 'Per GCL LAB reconciliation: Saliva: sample dated 10FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' (Site from DM).		08 Apr 2021 08:08:30
Query 'Per GCL LAB reconciliation: Saliva: sample dated 10FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' answered with 'REQ NOT IN CHART. COULD NOT LOCATE TO VERIFY' (Site from DM).		06 Apr 2021 12:05:16

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:58:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: sample dated 10FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 11:25:28
		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '10 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:58:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:58:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 12feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).	(b) (4)	12 Apr 2021 12:23:46
Query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 12feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' answered with 'ppd is showing as received	(b) (4), (b) (6)	09 Apr 2021 19:52:20
accession # 1F604561147' (Site from DM).		
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 12feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).		08 Apr 2021 08:10:14
User closed query 'Per GCL LAB reconciliation: Saliva: sample dated 12FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).		08 Apr 2021 08:10:00
Query 'Per GCL LAB reconciliation: Saliva: sample dated 12FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'REQ NOT IN CHART. COULD NOT LOCATE TO VERIFY' (Site from DM).		06 Apr 2021 12:05:43

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: sample dated 12FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). User entered '12 Feb 2021'	(b) (4), (b) (6)	05 Apr 2021 11:25:44
		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:58:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:58:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 17feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).	(b) (4)	12 Apr 2021 12:25:05
Query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 17feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' answered with 'ppd is showing as received	(b) (4), (b) (6)	09 Apr 2021 19:52:44
accession # 1F602399867' (Site from DM).		
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 17feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).		08 Apr 2021 08:19:50
User closed query 'Per GCL LAB reconciliation: Saliva: sample dated 17FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).		08 Apr 2021 08:10:30
Query 'Per GCL LAB reconciliation: Saliva: sample dated 17FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'REQ NOT IN CHART. COULD NOT LOCATE TO VERIFY' (Site from DM).		06 Apr 2021 12:06:10

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: sample dated 17FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). User entered '17 Feb 2021'	(b) (4), (b) (6)	05 Apr 2021 11:25:57
		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:58:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:58:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 24feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 12:25:10
Query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 24feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' answered with 'ppd is showing as received	(b) (4), (b) (6)	09 Apr 2021 19:53:07
accession # 1F606588027' (Site from DM).		
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : Sample dated 24feb2021 is still missing in PPD. If the sample was collected and not submitted to site for evaluation in the study, then please review and confirm if the Was sample collected? needs to be amended to "No" and Date of collection needs to amended. Else please provide the Accession # and Tracking number with the shipping date to track the sample in PPD.' (Site from DM).		08 Apr 2021 08:20:06
User closed query 'Per GCL LAB reconciliation: Saliva: sample dated 24FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).		08 Apr 2021 08:19:54
Query 'Per GCL LAB reconciliation: Saliva: sample dated 24FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'REQ NOT IN CHART. COULD NOT LOCATE IN CHART' (Site from DM).		06 Apr 2021 12:06:45

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EAB) (1725)

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US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: sample dated 24FEB2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). User entered '24 Feb 2021'	(b) (4), (b) (6)	05 Apr 2021 11:26:08
		22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:58:24

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:58:24

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:59:05

US3052312

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab Sample: Per Preclarus report there are 2 Illness Swab samples dated 04-Feb-2021(Illness D1[1]) and 24-Feb-2021(Illness D28[1]). However, this Swab data is missing in EDC. Kindly review Preclarus and make updates in EDC by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' (Site from DM).		26 Apr 2021 10:28:49
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab Sample: Per Preclarus report there are 2 Illness Swab samples dated 04-Feb-2021(Illness D1[1]) and 24-Feb-2021(Illness D28[1]). However, this Swab data is missing in EDC. Kindly review Preclarus and make updates in EDC by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' answered with 'covid assessment is already made with all of the information.' (Site from DM).		22 Apr 2021 13:38:08
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab Sample: Per Preclarus report there are 2 Illness Swab samples dated 04-Feb-2021(Illness D1[1]) and 24-Feb-2021(Illness D28[1]). However, this Swab data is missing in EDC. Kindly review Preclarus and make updates in EDC by initiating a Covid-19 Assessment page. Else, clarify. Thank you.' (Site from DM).		16 Apr 2021 04:30:59
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:49:53

US3052312

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:49:53

US3052312

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:49:53

US3052312

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User entered 'SICKD1'	System	22 Mar 2021 16:49:53

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	22 Mar 2021 16:51:49
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	22 Mar 2021 16:51:49
User entered '4 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:51:49
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	22 Mar 2021 16:51:24
User entered '9 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '16:30'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User entered '4 Feb 2021 16:30'	System	22 Mar 2021 16:51:49
User entered '9 Feb 2021 16:30'	System	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24
DataPoint set to visible.	System	22 Mar 2021 16:49:53

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24
DataPoint set to visible.	System	22 Mar 2021 16:49:53

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '87'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User entered 'bpm'	System	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '18'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User entered 'breaths/min'	System	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '132'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User entered 'mmHg'	System	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '76'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User entered 'mmHg'	System	22 Mar 2021 16:51:24

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21

US3052312

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21

US3052312

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:52:10

US3052312

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:52:10

US3052312

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:58:24

[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 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:53:10

US3052312

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:04:21
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 MAR 2021 is reported under Convalescence Visit Day 28 in EDC, however the sample dated 04 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 02:14:34
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 MAR 2021 is reported under Convalescence Visit Day 28 in EDC, however the sample dated 04 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' answered with 'INCORRECT DATE OF VISIT. UPDATED IN PPD. REQ EMAILED' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:09:09
User entered '4 Feb 2021' reason for change: Data Entry Error		06 Apr 2021 12:08:51
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 04 MAR 2021 is reported under Convalescence Visit Day 28 in EDC, however the sample dated 04 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab. Please review and confirm the correct date, update as appropriate. Else Clarify, Thank you.' (Site from DM).		05 Apr 2021 07:48:13
User entered '4 Mar 2021'		22 Mar 2021 16:53:10

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:53:51

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:53:51

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:53:51

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered 'SICKD28'	System	22 Mar 2021 16:53:51

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '14:19'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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 '26 Feb 2021 14:19'	System	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '74' in	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17
DataPoint set to visible.	System	22 Mar 2021 16:53:51

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '242' lb	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17
DataPoint set to visible.	System	22 Mar 2021 16:53:51

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '87'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User entered 'bpm'	System	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '18'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '118'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '80'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[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	22 Mar 2021 16:55:17

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:29

US3052312

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:29

US3052312

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 14:58:24

[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
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:50

US3052312

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 14:58:24

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:10:58
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 16:55:50

US3052312

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

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:44

US3052312

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

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:44

US3052312

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

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:26:44

US3052312

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

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 20:26:44

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[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 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 19:00:10
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:19
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:16:45

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		12 Apr 2021 15:44:19
User signature succeeded.	Yaa Oppong (b) (4)	09 Apr 2021 19:00:10
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'corrected' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:10:26
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 18:10:19
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		08 Apr 2021 18:54:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:16:45

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:36:05
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 03:36:05
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '1'	System	19 Jan 2021 20:27:12

US3052312

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

Form: Unblinding

Generated On: 09 Jun 2021 14:58:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'I'	System	19 Jan 2021 20:27:12

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '188' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '111' kg	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '31.40561'	System	19 Jan 2021 20:29:15
DataPoint set to visible.	System	19 Jan 2021 20:27:12

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '188' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '111' kg	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '31.40561'	System	19 Jan 2021 20:29:15
DataPoint set to visible.	System	19 Jan 2021 20:27:12

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User accepted default value 'Pre-Dose (PREDOSE)'		19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '13:14'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '16 Jan 2021 13:14'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '72'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'bpm'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'breaths/min'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '138'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'mmHg'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '82'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'mmHg'	System	19 Jan 2021 20:29:15

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '188' cm	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '111' kg	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:58:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '31.40561'	System	19 Jan 2021 20:29:15
DataPoint set to visible.	System	19 Jan 2021 20:27:12

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User accepted default value 'Post-Dose (POSTDOSE)'		19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '14:43'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '16 Jan 2021 14:43'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '67'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'bpm'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '12'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'breaths/min'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '142'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'mmHg'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '90'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:15

US3052312

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'mmHg'	System	19 Jan 2021 20:29:15

US3052312

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:29

US3052312

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:29

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

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 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'mRNA-1273'	System	19 Jan 2021 20:29:56
DataPoint set to visible.	System	19 Jan 2021 20:27:12

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '14:06'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '16 Jan 2021 14:06'	System	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'ONCE'	System	19 Jan 2021 20:29:56

US3052312

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

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 20:29:56

US3052312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:30:31

US3052312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:30:31

US3052312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '15:58'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:30:31

US3052312

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '16 Jan 2021 15:58'	System	19 Jan 2021 20:30:31

US3052312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:30:44

US3052312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:30:44

US3052312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:58:24

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '14:01'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:30:44

US3052312

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:58:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '16 Jan 2021 14:01'	System	19 Jan 2021 20:30:44

US3052312

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

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:30:49

US3052312

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

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'I'	System	19 Jan 2021 20:30:49

US3052312

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:17:42

US3052312

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data correct' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:48:52 15 Mar 2021 12:17:56
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Mar 2021 12:17:42
User entered '2 Feb 2021'	(b) (4), (b) (6)	15 Mar 2021 12:17:42

US3052312

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:17:42

US3052312

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:17:42

US3052312

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:18:04

US3052312

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'I'	System	15 Mar 2021 12:18:04

US3052312

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '1'	System	15 Mar 2021 12:18:04
DataPoint set to visible.	System	15 Mar 2021 12:18:04

US3052312

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:33

US3052312

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:33

US3052312

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:33

US3052312

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'OLD29'	System	30 Mar 2021 19:41:33

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User accepted default value 'Pre-Dose (PREDOSE)'		30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '12:55'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered '12 Feb 2021 12:55'	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 19:43:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Mar 2021 19:43:16
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:43:16
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 19:41:57
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 19:43:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Mar 2021 19:43:16
User entered '75' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:43:16
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 19:41:57
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'bpm'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 19:43:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Mar 2021 19:43:16
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:43:16
User opened query 'Data is required. Please provide.' (Site from System).		30 Mar 2021 19:41:57
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'breaths/min'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 19:43:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Mar 2021 19:43:16
User entered '128' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:43:16
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 19:41:57
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'mmHg'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 19:43:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	30 Mar 2021 19:43:16
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:43:16
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 19:41:57
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'mmHg'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User accepted default value 'Post-Dose (POSTDOSE)'		30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Mar 2021 19:43:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 19:43:16
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Mar 2021 19:41:57
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '13:55' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered '12 Feb 2021 13:55'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '98.2' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:16
User entered empty.		30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '72' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'bpm'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '18' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'breaths/min'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '132' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:16
User entered empty.		30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'mmHg'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '86' reason for change: Data Entry Error	(b) (4)	30 Mar 2021 19:43:16
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'mmHg'	System	30 Mar 2021 19:43:16
User entered empty.	System	30 Mar 2021 19:41:57

US3052312

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:26

US3052312

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:26

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

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 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'mRNA-1273'	System	30 Mar 2021 19:43:42
DataPoint set to visible.	System	15 Mar 2021 12:18:04

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '13:16'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered '12 Feb 2021 13:16'	System	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:26:38
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'per pt request' (Site from System).		30 Mar 2021 19:50:34
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	30 Mar 2021 19:43:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'ONCE'	System	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:58:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 19:43:42

US3052312

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:47:58

US3052312

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'I'	System	22 Mar 2021 14:47:58

US3052312

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:49:12

US3052312

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:49:12

US3052312

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:49:12

US3052312

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:58:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'MISSED'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:49:12

US3052312

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:48:09

US3052312

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:58:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'I'	System	22 Mar 2021 14:48:09

US3052312

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:48:30

US3052312

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:48:30

US3052312

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[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 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:48:30

US3052312

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:58:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered 'OLD57'	System	22 Mar 2021 14:48:30

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '14:21'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered '19 Mar 2021 14:21'	System	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '85'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'bpm'	System	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '17'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'breaths/min'	System	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '116'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'mmHg'	System	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '73'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04
User entered 'mmHg'	System	22 Mar 2021 14:49:42

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04

US3052312

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:58:24

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:04

US3052312

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:50:05

US3052312

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:50:05

US3052312

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:50:43

US3052312

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:50:43

US3052312

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:43:42
User entered '15:11'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 14:50:43

US3052312

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:48:03
User entered '19 Mar 2021 15:11'	System	22 Mar 2021 14:50:43

US3052312

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:58:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:43
User closed query 'Per CDM, DM CLR RQ on Safety Follow-up Diary Day 159 (01 Feb 2021) and Day 180 (21 Feb 2021): Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES. Previous site response indicates " AE WAS UPDATED FOR CONDITION"; however, there is no AE recorded with dates close to these diary entries. Please review if a medically-attended AE should be recorded or provide further clarification. Thank you. ' (Site from DM).		28 Apr 2021 06:21:59
Query 'Per CDM, DM CLR RQ on Safety Follow-up Diary Day 159 (01 Feb 2021) and Day 180 (21 Feb 2021): Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES. Previous site response indicates " AE WAS UPDATED FOR CONDITION"; however, there is no AE recorded with dates close to these diary entries. Please review if a medically-attended AE should be recorded or provide further clarification. Thank you. ' answered with 'subject stated it was for follow up appointment. ' (Site from DM).		22 Apr 2021 13:44:59
User opened query 'Per CDM, DM CLR RQ on Safety Follow-up Diary Day 159 (01 Feb 2021) and Day 180 (21 Feb 2021): Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES. Previous site response indicates " AE WAS UPDATED FOR CONDITION"; however, there is no AE recorded with dates close to these diary entries. Please review if a medically-attended AE should be recorded or provide further clarification. Thank you. ' (Site from DM).		15 Apr 2021 07:46:23
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	08 Apr 2021 20:31:42

US3052312

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:58:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 12:43:02

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 17:38:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 17:38:38
Data point term sent to Coder	System	01 Apr 2021 17:38:02
User entered 'SINUS INFECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:38:01
Data point term sent to Coder	System	01 Apr 2021 17:38:01
User entered 'sinus infectrion'	(b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.		16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
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)	01 Apr 2021 17:38:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:38:01
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	01 Apr 2021 17:37:31
User entered '00:00'	(b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
User entered empty.	System	01 Apr 2021 17:38:01
User entered '24 Nov 2020 00:00'	System	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	01 Apr 2021 17:38:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:38:01
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	01 Apr 2021 17:37:31
User entered '00:00'	(b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
User entered empty.	System	01 Apr 2021 17:38:01
User entered '26 Nov 2020 00:00'	System	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.		16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	15 Apr 2021 16:31:47
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 07:42:46
' (Site from DM).		
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify.	(b) (4), (b) (6)	14 Apr 2021 15:26:09
' answered with 'updated' (Site from DM).		
Signature has been broken.		14 Apr 2021 15:26:03
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		14 Apr 2021 15:26:03
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate, else clarify.		10 Apr 2021 07:13:00
' (Site from DM).		
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'l'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	08 Apr 2021 20:31:42
User entered 'subject does not remember what antibiotic he was prescribed'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
User entered '0'	System	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06
User entered 'I'	System	01 Apr 2021 17:37:31

US3052312

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:58:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:47:06

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
User entered 'USA-US117-2021-mRNA-1273-P301000009'	(b) (4) System	19 Apr 2021 17:06:54
User entered 'New'	(b) (4), (b) (6)	19 Apr 2021 17:06:54

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Arthritis bacterial, LLT: Septic joint - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:35:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:35:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4) (b) (4)	16 Apr 2021 15:26:32
Data point term sent to Coder	System	16 Apr 2021 14:51:18
User entered 'septic right knee'	(b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'PER CDM: Response noted, however RELATIONSHIP TO IP and RELATIONSHIP TO STUDY PROCEDURE are both recorded as NOT RELATED. Kindly review entries according to CCG's and provide update. ' (Sit from DM).	(b) (4), (b) (6)	28 Apr 2021 06:13:37
Query 'PER CDM: Response noted, however RELATIONSHIP TO IP and RELATIONSHIP TO STUDY PROCEDURE are both recorded as NOT RELATED. Kindly review entries according to CCG's and provide update. ' answered with 'updated' (Site from DM).		22 Apr 2021 13:42:02
DataPoint Un-verified.		22 Apr 2021 13:41:51
Signature has been broken.		22 Apr 2021 13:41:51
User entered 'No (N)' reason for change: Data Entry Error		22 Apr 2021 13:41:51
User opened query 'PER CDM: Response noted, however RELATIONSHIP TO IP and RELATIONSHIP TO STUDY PROCEDURE are both recorded as NOT RELATED. Kindly review entries according to CCG's and provide update. ' (Site from DM).		20 Apr 2021 14:59:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:50:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:52
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	16 Apr 2021 14:51:16
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	16 Apr 2021 14:50:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	16 Apr 2021 14:51:16
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).		16 Apr 2021 14:51:16
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:51:16
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	16 Apr 2021 14:50:53
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:50:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query '(Re-query) PV Query: discharge date was reported as 29 Jan 2021 in EDC and 31 Jan 2021 in paper SAE form. Please reconcile.' answered with 'The correct discharge date is 29 Jan 2021. The date of 31 Jan 2021 was entered on the paper SAE for in error.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 17:05:53
User opened query '(Re-query) PV Query: discharge date was reported as 29 Jan 2021 in EDC and 31 Jan 2021 in paper SAE form. Please reconcile.' (Site from Safety).		30 Apr 2021 21:34:37
Query 'No update in Argus' canceled (Site from Safety).		30 Apr 2021 21:34:22
User opened query 'No update in Argus' (Site from Safety).		30 Apr 2021 21:34:17
User closed query 'PV Query: discharge date was reported as 29 Jan 2021 in EDC and 31 Jan 2021 in paper SAE form. Please reconcile.' (Site from Safety).		30 Apr 2021 21:34:17
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please leave query open until information is received.' canceled (Site from Safety).		30 Apr 2021 21:33:08
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. Please leave query open until information is received.' (Site from Safety).		30 Apr 2021 21:32:49
Query 'PV Query: discharge date was reported as 29 Jan 2021 in EDC and 31 Jan 2021 in paper SAE form. Please reconcile.' answered with 'Subject was discharged from the hospital 29 JAN 2021. Subject went back with complications on 31 JAN 2021 but not admitted. Discharge date of 31 JAN 2021 was entered in error.' (Site from Safety).		30 Apr 2021 20:00:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: discharge date was reported as 29 Jan 2021 in EDC and 31 Jan 2021 in paper SAE form. Please reconcile.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:28:36
	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered '29 Jan 2021'	(b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please specify antibiotics given. Please leave query open until information is received.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 16:28:55
	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 14:50:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (blood culture etc). Please include units and reference ranges if applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:28:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		27 Apr 2021 18:49:43
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		27 Apr 2021 18:49:39
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		27 Apr 2021 18:49:31
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'medical records have been requested for the 2nd time stating medications' (Site from Safety).		27 Apr 2021 16:31:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records have been requested for the 2n time laboratory testing' (Site from Safety).		27 Apr 2021 16:31:35
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'medical records have been requested for the 2nd time stating covid testing' (Site from Safety).		27 Apr 2021 16:31:05

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 16:30:26
Signature has been broken.		27 Apr 2021 16:30:26
User entered 'subject had a covid nasal swab on 27jan2021 and 31jan2021 both were negative. subject had blood cultures drawn everyday he was in the hospital. subject was not given any surgery. he was on IV drip all 5 days. subject does not remember the names of the medications. medical records have been requested.' reason for change: Data Entry Error		27 Apr 2021 16:30:26
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 16:03:03
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		23 Apr 2021 16:02:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		23 Apr 2021 16:02:27
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		23 Apr 2021 16:02:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:33:55
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 14:50:53

US3052312

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:58:24

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 14:50:53

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:43
User closed query 'Per CDM DM CLR Re-query: Per response however there is no update reflecting in the Ae page for Safety follow up dairy Day 159 and Day 180. Kindly review and amend as appropriate.' (Site from DM).		15 Apr 2021 07:46:28
Query 'Per CDM DM CLR Re-query: Per response however there is no update reflecting in the Ae page for Safety follow up dairy Day 159 and Day 180. Kindly review and amend as appropriate.' answered with 'CHECK AE PAGE. AE WAS UPDATED FOR CONDITION' (Site from DM).		06 Apr 2021 12:11:00
User opened query 'Per CDM DM CLR Re-query: Per response however there is no update reflecting in the Ae page for Safety follow up dairy Day 159 and Day 180. Kindly review and amend as appropriate.' (Site from DM).		02 Apr 2021 16:51:36
User closed query '(QUERY FOR AE PAGE) Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded in the AE eCRF, otherwise provide clarification.' (Site from DM).		02 Apr 2021 16:51:36
User closed query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		02 Apr 2021 16:21:31

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
Query '(QUERY FOR AE PAGE) Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded in the AE eCRF, otherwise provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:45:05
Query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'updated' (Site from DM).		01 Apr 2021 12:45:02
User opened query '(QUERY FOR AE PAGE) Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded in the AE eCRF, otherwise provide clarification.' (Site from DM).		25 Mar 2021 04:31:27
User opened query '(QUERY FOR AE PAGE) Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		20 Mar 2021 05:14:51

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:58:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:03:50

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 19:10:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 19:10:50
Data point term sent to Coder	System	01 Sep 2020 19:09:33
User entered 'Fenofibrate'	(b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'High Cholesterol'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '160'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

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

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 12:47:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 12:47:06
User entered 'No (N)' reason for change: Data Entry Error	Avia McClain-Stocker (b) (4)	20 Oct 2020 12:47:06
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:08:46
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:58:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 19:08:46

US3052312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:58:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:10:43
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 14:07:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 14:07:45
User signature succeeded.	Yaa Oppong (b) (4)	19 Mar 2021 16:53:08
	(b) (4)	
User entered 'No (N)'	Avia McClain-Stocker	26 Oct 2020 12:15:37
	(b) (4)	

US3052312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:58:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered '16 Feb 2021'	(b) (4), (b) (6)	16 Apr 2021 14:08:18

US3052312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:58:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'ENDOSCOPIC PROCEDURE for vocal cords' reason for change: Data Entry Error	(b) (4)	16 Apr 2021 14:08:46
User entered 'endoscopic procedure'	(b) (4), (b) (6)	16 Apr 2021 14:08:18

US3052312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:58:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:08:18

US3052312

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:58:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	16 Apr 2021 15:26:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 14:08:18

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'USA-US117-2021-MRNA-1273-P301000009'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yes (Y)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yes (Y)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yaa'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Oppong'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered '1565 Purdue Drive'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Fayetteville'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'NC'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered '28314'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
User entered 'US'	(b) (4) System	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 18:50:26
User entered '1'	System	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'USA-US117-2021-MRNA-1273-P301000009'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yes (Y)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yes (Y)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yaa'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Oppong'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered '1565 Purdue Drive'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Fayetteville'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'NC'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered '28314'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
User entered 'US'	(b) (4) System	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 18:50:26
User entered '1'	System	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:58:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
User entered '19/Apr/2021 13:08'	(b) (4) System	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:58:24

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)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'USA-US117-2021-MRNA-1273-P301000009'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yes (Y)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yes (Y)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'No (N)'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Yaa'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Oppong'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered '1565 Purdue Drive'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'Fayetteville'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered 'NC'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:08:47
User entered '28314'	System	19 Apr 2021 17:06:54

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	20 Apr 2021 02:12:42
User entered 'US'	(b) (4) System	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:58:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Apr 2021 18:50:26
User entered '1'	System	19 Apr 2021 17:08:56

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:58:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 21:08:09
User entered '27/Apr/2021 14:50'	(b) (4) System	27 Apr 2021 18:50:26

US3052312

Folder: SAE USA-US117-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:58:24

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)
User signature succeeded.	Yaa Oppong (b) (4)	28 Apr 2021 21:08:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 18:50:26