

US3212016 (Prod: DM Clinical Research - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:47:01

All time stamps listed in this document are displayed in GMT

US3212016

Form: Participant Creation

Generated On: 26 Nov 2020 10:47:01

[Participant ID](#)

US3212016

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

US3212016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:47:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3212016

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:47:01

Were any significant conditions reported?

Yes ☒

No ☐

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

Condition	MODERATE ASTHMA
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	
Stop Year (derived)	

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:26 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 15:26
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	240 lb
BMI (<i>xxx.x</i>)	37.66791 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 AUG 2020

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

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

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

LANDSCAPING
SUPERINTENDENT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) True

v6.020 DTW (1102)

14 of 2307

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PEOPLE IN THE PARTICIPANT'S WORKPLACE ARE NOT REGULARLY USING PERSONAL PROTECTION EQUIPMENT (MASKS, GLOVES, ETC)

US3212016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 142705

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 ☒

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:47:01

Height	ND - Not Done
Weight	ND - Not Done

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	15:26 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 15:26
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

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)	03 AUG 2020
Time of assessment (00:00-23:59)	17:34 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 17:34
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3212016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

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) 03 AUG 2020

What was the treatment time? (00:00-23:59) 16:44 (24 HR)

Treatment Date and Time (derived) 03 AUG 2020 16:44

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

US3212016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	3 AUG 2020
Collection time (<i>00:00-23:59</i>)	16:43 (24 HR)
Collection date and time (derived)	3 AUG 2020 16:43

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:47:01

Collection date (<i>dd MMM yyyy</i>)			3 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:37	3 AUG 2020 16:37
Nasopharyngeal Swab 2	No		

US3212016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 17:32

PC Open Date & Time

03 AUG 2020 17:04

PC Close Date & Time

03 AUG 2020 19:34

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	04 AUG 2020 09:09
PC Open Date & Time	03 AUG 2020 20:29
PC Close Date & Time	04 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.2 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	04 AUG 2020 20:09
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.5 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	05 AUG 2020 18:04
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

100.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 AUG 2020 19:32

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

100.4 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 AUG 2020 17:41

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

98.5 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 AUG 2020 06:05

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

99.3 °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

09 AUG 2020 18:08

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

03 AUG 2020 17:33

PC Open Date & Time

03 AUG 2020 17:04

PC Close Date & Time

03 AUG 2020 19:34

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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

8

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

04 AUG 2020 09:21

PC Open Date & Time

03 AUG 2020 20:29

PC Close Date & Time

04 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

04 AUG 2020 20:10

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

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

05 AUG 2020 18:04

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

06 AUG 2020 19:33

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

07 AUG 2020 17:42

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

09 AUG 2020 06:06

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

09 AUG 2020 18:09

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 17:34
PC Open Date & Time	03 AUG 2020 17:04
PC Close Date & Time	03 AUG 2020 19:34

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 09:22
PC Open Date & Time	03 AUG 2020 20:29
PC Close Date & Time	04 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

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 ☒

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:11
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

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 ☒

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 18:05
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

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 ☒

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:36
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

		Yes <input type="radio"/>
PC Time stamp	07 AUG 2020 17:44	
PC Open Date & Time	07 AUG 2020 12:00	
PC Close Date & Time	08 AUG 2020 11:59	

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

	Yes <input type="radio"/>
PC Time stamp	09 AUG 2020 06:07
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

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 ☒

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 11 AUG 2020 12:07

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 12 AUG 2020 18:55

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 11 AUG 2020 12:07

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

12 AUG 2020 18:55

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp 14 AUG 2020 06:19

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 8

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 AUG 2020 12:07

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 10

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

12 AUG 2020 18:55

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

PC Time stamp 11 AUG 2020 12:07

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/>
	Yes <input type="radio"/>
PC Time stamp	
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 AUG 2020 12:08
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 AUG 2020 18:56
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3212016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

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

PARTICIPANT IS IN
CONVALESCENT/ILLNESS
PERIOD

If Contact Not Made, please provide Comments

US3212016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

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)	11 SEP 2020
Time of assessment (00:00-23:59)	17:48 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 17:48
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (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	

US3212016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3212016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 SEP 2020
Collection time (<i>00:00-23:59</i>)	18:13 (24 HR)
Collection date and time (derived)	11 SEP 2020 18:13

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:47:01

Collection date (<i>dd MMM yyyy</i>)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:10	11 SEP 2020 18:10
Nasopharyngeal Swab 2	No		

US3212016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:01 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 16:01
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3212016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	16 OCT 2020
Collection time (<i>00:00-23:59</i>)	16:14 (24 HR)
Collection date and time (derived)	16 OCT 2020 16:14

US3212016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

13 OCT 2020 11:34:35

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

20 OCT 2020 09:44:27

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 17:06:00

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 99
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	11 NOV 2020 09:31:56
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 12:00:31

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 61
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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 68
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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

07 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

20 NOV 2020 18:24:51

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 117

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 131

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 145

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Patient Cloud Open Date & Time	23 DEC 2020 00:01
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Patient Cloud Close Date & Time	27 DEC 2020 23:59
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US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 159

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 <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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

24 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 <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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

07 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	25 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 537

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 621

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 MAY 2022 00:01
Patient Cloud Close Date & Time	29 MAY 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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="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"/>

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

DAY 796

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

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

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

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

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

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

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

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

Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	09 OCT 2022 23:59
---	-------------------

US3212016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3212016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3212016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:47:01

Date of Contact	7 AUG 2020
Time of Contact	16:49
Date and Time of Contact (derived)	7 AUG 2020 16:49
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

	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	04 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	320 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
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"/>
<hr/>		
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
<hr/>		
Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.5 F	
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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	324 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	328 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	332 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

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 checked="" 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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	336 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

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 checked="" 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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	340 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

	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 type="radio"/>
	Mild	<input checked="" 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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	344 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	348 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	352 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

	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 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	356 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

	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	17 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	360 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

	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	18 AUG 2020	
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 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	364 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

	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	19 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	368 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

	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"/>
Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

	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	20 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 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"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	372 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

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

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

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

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

New Loss of Taste	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
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"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

	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	05 AUG 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	376 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

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

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

	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	06 AUG 2020	
Assessment Not Done	True	
O2 Saturation	<hr/>	
O2 Saturation Units	<hr/>	
Temperature	<hr/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	380 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[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"/>
Day 33	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

	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	07 AUG 2020	
Assessment Not Done	True	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	384 of 2307	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

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

Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

Date of Visit	7 AUG 2020
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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	07 AUG 2020
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)	1

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

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

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date _____

Hepatic Dysfunction? Yes ☐
No ☐

Start Date _____

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

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

Start Date

End Date

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:47:01

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	9 AUG 2020
Day 5	Yes	11 AUG 2020
Day 7	Yes	13 AUG 2020
Day 9	Yes	15 AUG 2020
Day 14	Yes	20 AUG 2020
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3212016

Folder: Illness Visit (2)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (3)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (4)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (5)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (6)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (7)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (8)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (9)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (10)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (11)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (12)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (13)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (14)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit (15)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:47:01

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	SICKD1

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:45 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 16:45
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	240 lb
Temperature (<i>xxx.x</i>)	100.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 AUG 2020

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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US3212016

Folder: Illness Visit Day 1 (1)

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

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SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
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If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

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

Folder OID	SICKD28
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Were vital signs assessed?	Yes <input type="checkbox"/>
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Date of assessment (<i>dd MMM yyyy</i>)	
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Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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US3212016

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
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	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

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Was the physical examination performed?

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Date of examination (dd MMM yyyy)

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Folder: Convalescence Visit Day 28 (1)

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Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

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Form: Vital Signs

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Date of assessment (<i>dd MMM yyyy</i>)	
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Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
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Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

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Was the physical examination performed?

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Date of examination (dd MMM yyyy)

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Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
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	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

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Was this visit performed? Yes ☐
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Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

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Time of assessment (<i>00:00-23:59</i>)	
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Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

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SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
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Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

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Time of assessment (<i>00:00-23:59</i>)	
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Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

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Date of examination (dd MMM yyyy)

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Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

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Was this visit performed? Yes ☐
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Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Were vital signs assessed?	Yes <input type="checkbox"/>
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Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
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Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
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Height (derived)	
Weight (derived)	

US3212016

Folder: Convalescence Visit Day 28 (1)

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SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

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Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

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Were vital signs assessed?	Yes <input type="checkbox"/>
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Temperature (<i>xxx.x</i>)	
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Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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US3212016

Folder: Convalescence Visit Day 28 (1)

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

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Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes <input type="checkbox"/>
SARS_COV-2 Infection?	No <input type="checkbox"/>
	NA (COVID-19 Negative) <input type="checkbox"/>

Date of Collection	
--------------------	--

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

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.

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
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US3212016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:47:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

AEID	
Adverse event	WORSENING HYPERTENSION
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)	10 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

528 of 2307

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

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

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:47:01

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

Yes ☒

No ☐

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

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	GASTROESOPHAGEAL REFLUX DISEASE
Dose per administration	20
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	SYMBICORT (BUDESONIDE/FORMOTEROL FUMARATE)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	80/4.5
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	VENTOLIN (ALBUTEROL)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	180
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID-19
Dose per administration	600
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		4 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		10 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	MUCINEX
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID-19
Dose per administration	600
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		06 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		11 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

Name of Medication NYQUIL
(ACETAMINOPHEN/DEXTROME
THORPHAN/DOXYLAMINE)

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 325/15/6.25

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 ☐

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	7 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID-19
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

	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)		9 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	ZINC SULFATE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	COVID19/HEALTH SUPPLEMENT
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 AUG 2020
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"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	AMLODIPINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	WORSENING HYPERTENSION
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		10 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID-19
Dose per administration	250
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

	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)		10 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3212016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:47:01

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3212016

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:47:01

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

Case Report Form

Visit Date	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	
Vital Signs	
Vital Signs - Dosing	
Physical Examination	
Central Laboratory - Nasopharyngeal Swab	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Immunogenicity Assessment	
Saliva Collection	
COVID Diagnostic Test	
Symptom Log	
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	
COVID-19 Severity Assessment	
COVID-19 Contact	
Risk of Exposure	
Safety Call	
Dosing Discontinuation	
End of Study / Study Discontinuation	

US3212016

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 10:47:01

All	
Date of missed or out of window visit or assessment	
Category	
Inclusion criteria not met/Exclusion criteria met	
Study Treatment not given	
Missed Visit	
Missed Assessment	
Visit performed out of window	
Assessment performed out of window	
Scheduled clinical visit performed as home visit	
Other	
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	
Travel restrictions	
Quarantine due to COVID-19	
Possible exposure to COVID-19	
Exposure to COVID-19	
Presumption / confirmed COVID-19	
Symptoms of COVID-19	
Sponsor hold due to COVID-19	
Participant decision	

US3212016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:47:01

Date of dosing discontinuation (dd MMM yyyy)

07 AUG 2020

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

US3212016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:47:01

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 ☐

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

SAEID	USA-US115-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:47:01

SAEID	USA-US115-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/AUG/2020 13:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:47:01

SAEID	USA-US115-2020-MRNA-1273-P301000001
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	VICKI
Investigator's Last Name	MILLER
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/AUG/2020 14:49
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

US3212016 (Prod: DM Clinical Research - ERN - PPDS)

US3212016

Form: Participant Creation

Generated On: 26 Nov 2020 10:47:01

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:21:29
User entered 'US3212016'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:19:14

US3212016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:21:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:21:49

US3212016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:05
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:19:14

US3212016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Aug 2020 21:21:49

US3212016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	03 Aug 2020 21:21:49

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered (b) (6) 1971'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:19:15

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '49'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '49'	System	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered 'Male (M)'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '1'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:47:01

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:22:53
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:22:42

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:23:35
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '2020'	System	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:23:35
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:23:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:23:35
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:23:35
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:23:35
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:24:45

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:23:35
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:19:14

US3212016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:47:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Aug 2020 21:25:14

US3212016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:24:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:25:14

US3212016

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:47:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:25:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:25:41

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:43:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:28:08
Data point term sent to Coder	System	03 Aug 2020 21:27:29
User entered 'Vasectomy'	(b) (4), (b) (6)	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:02
User entered 'UN UNK 2012'	(b) (4), (b) (6)	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:04
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:06
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:08
User entered 'UN UNK 2012'	(b) (4), (b) (6)	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:10
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '2012'	System	03 Aug 2020 21:27:17

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:29:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:29:08
Data point term sent to Coder	System	03 Aug 2020 21:28:30
User entered 'Moderate Asthma'	(b) (4), (b) (6)	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:40
User entered 'UN UNK 1982'	(b) (4), (b) (6)	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:37
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:44
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:44:46
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '1982'	System	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:27:47

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

Condition

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:46:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastrooesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:29:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:29:08
Data point term sent to Coder	System	03 Aug 2020 21:28:32
User entered 'Gastroesophageal Reflux Disease'	(b) (4), (b) (6)	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per source, start date is 00-000-2000. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:55:32
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:55:26
Query 'Per source, start date is 00-000-2000. Please verify and update accordingly.' answered with 'Data entry error' (Site from CRA).	Heather Leary (b) (4)	13 Aug 2020 14:49:20
User entered 'un UNK 2000' reason for change:	(b) (4)	
Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:49:12
User opened query 'Per source, start date is 00-000-2000. Please verify and update accordingly.' (Site from CRA).	(b) (4)	
User entered '3 Aug 2020'	(b) (4), (b) (6)	12 Aug 2020 19:45:47
	(b) (4), (b) (6)	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:46:00
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:45:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:46:04
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:45:59
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	13 Aug 2020 14:49:12
User entered 'Aug 2020'	System	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '2000'	System	13 Aug 2020 14:49:12
User entered '2020'	System	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:28:20

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

Condition

Audit	User	Time (GMT)
User closed query 'Per source, Subject has Hypertension. Please verify and update the Medical History accordingly.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:55:49
Query 'Per source, Subject has Hypertension. Please verify and update the Medical History accordingly.' answered with 'Reviewed and updated' (Site from CRA).	Heather Leary (b) (4) (b) (4)	13 Aug 2020 14:50:03
User opened query 'Per source, Subject has Hypertension. Please verify and update the Medical History accordingly.' (Site from CRA).	(b) (4), (b) (6)	12 Aug 2020 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:47:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:30:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:30:09
Data point term sent to Coder	System	03 Aug 2020 21:29:32
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:47:06
User entered 'UN UNK 2005'	(b) (4), (b) (6)	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:47:09
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:47:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:47:13
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:47:15
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '2005'	System	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:28:47

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:56:29
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 14:52:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Aug 2020 14:52:17
Data point term sent to Coder	System	13 Aug 2020 14:50:48
User entered 'Hypertension'	Heather Leary (b) (4)	13 Aug 2020 14:49:48
	(b) (4)	

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:56:31
User entered 'un UNK 2018'	Heather Leary (b) (4) (b) (4)	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:56:33
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:56:34
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:56:36
User entered empty.	Heather Leary (b) (4) (b) (4)	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:57:55
User entered '0'	Heather Leary (b) (4) (b) (4)	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '2018'	System	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 14:49:48

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:55:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:55:34
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:55:41
User entered '15:26'	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '3 Aug 2020 15:26'	System	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:55:16
User entered '67' in	(b) (4), (b) (6)	03 Aug 2020 21:36:00
DataPoint set to visible.	System	03 Aug 2020 21:25:14

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:55:21
User entered '240' lb	(b) (4), (b) (6)	03 Aug 2020 21:36:00
DataPoint set to visible.	System	03 Aug 2020 21:25:14

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '37.66791'	System	16 Sep 2020 23:41:50
User entered '37.7'	System	03 Aug 2020 21:36:00
DataPoint set to visible.	System	03 Aug 2020 21:25:14

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	03 Aug 2020 21:36:00
DataPoint set to visible.	System	03 Aug 2020 21:25:14

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Please remove the remaining vitals from this page and mark as 'ND'. (Only record Height and Weight on Screening visit, if Subject was Randomized same day as Screened)' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:57:03
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:57:01
Query 'Please remove the remaining vitals from this page and mark as 'ND'. (Only record Height and Weight on Screening visit, if Subject was Randomized same day as Screened)' answered with 'Updated' (Site from CRA).	Heather Leary (b) (4)	13 Aug 2020 14:50:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 14:50:44
User opened query 'Please remove the remaining vitals from this page and mark as 'ND'. (Only record Height and Weight on Screening visit, if Subject was Randomized same day as Screened)' (Site from CRA).	(b) (4), (b) (6)	12 Aug 2020 19:57:27
User entered '97.8' F	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Please remove data.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:44:06
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:44:01
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:03:30
Query 'Please remove data.' answered with 'done' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:52:04
User opened query 'Please remove data.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:57:16
User entered 'Other (Other)' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:50:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:44:03
DataPoint Un-verified.	Afifah Ayub (b) (4)	07 Oct 2020 17:03:30
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	07 Oct 2020 17:03:30
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:57:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:50:44
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:57:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:50:44
User entered '79'	(b) (4)	
	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:57:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:50:44
User entered '12'	(b) (4)	
	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:57:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:50:44
User entered '136'	(b) (4)	
	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:57:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:50:44
User entered '85'	(b) (4)	
	(b) (4), (b) (6)	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Aug 2020 21:36:00

US3212016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:58:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:36:12

US3212016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:31:37
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 13:30:41
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 12:48:37
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	20 Aug 2020 17:37:52
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	20 Aug 2020 17:37:52
DataPoint Un-verified.	Afifah Ayub (b) (4)	20 Aug 2020 17:37:52
User entered '03 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:37:52
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 22:09:55
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 19:59:22
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 21:36:12

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:42:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:42:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:42:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:41:08
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Other

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered 'Landscaping Superintendent'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered 'I'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:47:01

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:05:56
User entered 'People in the participant's workplace are not regularly using personal protection equipment (masks, gloves, etc)'	(b) (4), (b) (6)	03 Aug 2020 21:41:08

US3212016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:19:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:53:47

US3212016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	10 Nov 2020 14:03:40
	(b) (4)	
User entered '03 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	10 Nov 2020 14:03:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:19:30
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 21:53:47

US3212016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:19:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Aug 2020 21:53:47

US3212016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	03 Aug 2020 21:53:47

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:19:20

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:50:43
Amendment Manager: Data point set to conformant. DataPoint Verified.	System	21 Aug 2020 01:50:42
	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 21:19:20
User entered '142705' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:19:20

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 21:19:20

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:56:14

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:56:14

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:56:14

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:56:14

US3212016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:47:01

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:20:56
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:56:14

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:47:01

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:21:14
User entered missing code ND - Not Done.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:47:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:21:16
User entered missing code ND - Not Done.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:47:01

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:21:14
User entered missing code ND - Not Done.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:47:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:21:16
User entered missing code ND - Not Done.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:00
User entered 'Yes (Y)'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:02
User entered '03 Aug 2020'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '15:26'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '03 Aug 2020 15:26'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:06
User entered '97.8' F	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:09
User entered 'Oral (Oral)'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:10
User entered empty.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:13
User entered '79'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:15
User entered '12'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:19
User entered '136'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:22:21
User entered '85'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:47:01

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:21:14
User entered missing code ND - Not Done.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:47:01

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:21:16
User entered missing code ND - Not Done.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:23:41
User entered 'Yes (Y)'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:23:46
User entered '03 Aug 2020'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:23:55
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 11:04:05
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per page 73 of protocol vital signs will be measured at least 30 minutes after IP injection' (Site from System).	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:41:07
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 13:40:27
User entered '17:34'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '03 Aug 2020 17:34'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:24:12
User entered '98.9' F	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:24:16
User entered 'Oral (Oral)'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:24:18
User entered empty.	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:24:21
User entered '74'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:24:24
User entered '12'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:24:27
User entered '134'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:24:29
User entered '86'	Nirja Shah (b) (4) (b) (4)	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Aug 2020 13:40:27

US3212016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	20 Aug 2020 17:36:51
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:25:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Aug 2020 13:47:01
	(b) (4)	
User entered 'No (N)'	Nirja Shah (b) (4)	04 Aug 2020 13:41:17
	(b) (4)	

US3212016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	20 Aug 2020 17:36:51
	(b) (4)	
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	20 Aug 2020 17:36:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:25:26
User entered '3 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	04 Aug 2020 13:47:01
	(b) (4)	
User entered empty.	Nirja Shah (b) (4)	04 Aug 2020 13:41:17
	(b) (4)	

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:26:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:26:45
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:26:45
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 21:47:34
Query 'Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' answered with 'UPDATED' (Site from DM).	Heather Leary (b) (4)	06 Nov 2020 20:42:57
DataPoint Un-verified.	(b) (4)	
User entered '03 Aug 2020' reason for change: Data Entry Error	Heather Leary (b) (4)	06 Nov 2020 20:42:50
User opened query 'Per CDM: Per CCGs Date should be entered in (DD-MMM-YYYY) format, Please review and update or comment accordingly. ' (Site from DM).	(b) (4)	06 Nov 2020 20:38:05
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:26:45
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:26:45
User entered '16:44'	(b) (4), (b) (6)	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 16:44'	System	06 Nov 2020 20:42:50
User entered '3 Aug 2020 16:44'	System	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:26:45
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:26:45
User entered 'ONCE'	System	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 22:01:09

US3212016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:27:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:57:14

US3212016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:27:17
User entered '3 Aug 2020'	(b) (4), (b) (6)	03 Aug 2020 21:57:14

US3212016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:27:22
User entered '16:43'	(b) (4), (b) (6)	03 Aug 2020 21:57:14

US3212016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Aug 2020 16:43'	System	03 Aug 2020 21:57:14

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:47:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	03 Aug 2020 21:58:17
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	03 Aug 2020 21:58:17
User entered '3 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:58:17
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	03 Aug 2020 21:57:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:28:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:28:03
User entered '16:37'	(b) (4), (b) (6)	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Aug 2020 16:37'	System	03 Aug 2020 21:58:17
User entered empty.	System	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:52:40
User entered 'No (N)' reason for change: Data Entry Error	Laura Ngansop Djampou (b) (4)	25 Aug 2020 19:52:40
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:28:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	Laura Ngansop Djampou	25 Aug 2020 19:52:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou	25 Aug 2020 19:52:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:28:31
	(b) (4), (b) (6)	
User entered '16:37'	(b) (4), (b) (6)	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:52:40
User entered '3 Aug 2020 16:37'	System	03 Aug 2020 21:58:17
User entered empty.	System	03 Aug 2020 21:57:52

US3212016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	18 Aug 2020 19:23:17

US3212016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 19:23:17

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:31:52', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'c02d1cdf-9d28-4d25-a241-6eb4d778ad30'	System	03 Aug 2020 22:32:17
User entered 'Yes (Y)'	System	03 Aug 2020 22:32:17

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:32:00', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'c02d1cdf-9d28-4d25-a241-6eb4d778ad30'	System	03 Aug 2020 22:32:17
User entered '98.9'	System	03 Aug 2020 22:32:17

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:32:06', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'c02d1cdf-9d28-4d25-a241-6eb4d778ad30'	System	03 Aug 2020 22:32:17
User entered 'No (N)'	System	03 Aug 2020 22:32:17

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:32:14', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'c02d1cdf-9d28-4d25-a241-6eb4d778ad30'	System	03 Aug 2020 22:32:17
User entered '03 Aug 2020 17:32'	System	03 Aug 2020 22:32:17

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 17:04'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 19:34'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:08:54', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '6fec4e66-cdda-482c-85dd-6f3c0b187100'	System	04 Aug 2020 14:09:27
User entered 'Yes (Y)'	System	04 Aug 2020 14:09:27

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:09:00', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '6fec4e66-cdda-482c-85dd-6f3c0b187100'	System	04 Aug 2020 14:09:27
User entered '98.6'	System	04 Aug 2020 14:09:27

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:09:07', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '6fec4e66-cdda-482c-85dd-6f3c0b187100'	System	04 Aug 2020 14:09:27
User entered 'No (N)'	System	04 Aug 2020 14:09:27

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:09:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '6fec4e66-cdda-482c-85dd-6f3c0b187100'	System	04 Aug 2020 14:09:27
User entered '04 Aug 2020 09:09'	System	04 Aug 2020 14:09:27

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 20:29'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 2'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:08:26', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '161f2389-005d-44ce-ad13-e2ffca53251d'	System	05 Aug 2020 01:09:37
User entered 'Yes (Y)'	System	05 Aug 2020 01:09:37

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:08:37', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '161f2389-005d-44ce-ad13-e2ffca53251d'	System	05 Aug 2020 01:09:37
User entered '100.2'	System	05 Aug 2020 01:09:37

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:08:48', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '161f2389-005d-44ce-ad13-e2ffca53251d'	System	05 Aug 2020 01:09:37
User entered 'Yes (Y)'	System	05 Aug 2020 01:09:37

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient contacted. Conmeds updated' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:51:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:09:12', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '161f2389-005d-44ce-ad13-e2ffca53251d'	Heather Leary (b) (4)	05 Aug 2020 14:54:41
User entered '1'	System	05 Aug 2020 01:09:37
	System	05 Aug 2020 01:09:37
	System	05 Aug 2020 01:09:37

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:09:12', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '161f2389-005d-44ce-ad13-e2ffca53251d'	System	05 Aug 2020 01:09:37
User entered '0'	System	05 Aug 2020 01:09:37

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:09:35', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '161f2389-005d-44ce-ad13-e2ffca53251d'	System	05 Aug 2020 01:09:37
User entered '04 Aug 2020 20:09'	System	05 Aug 2020 01:09:37

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 3'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:03:52', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd375e7bf-4c14-4f2e-88fa-422a944e0cbe'	System	05 Aug 2020 23:04:24
User entered 'Yes (Y)'	System	05 Aug 2020 23:04:24

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:00', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd375e7bf-4c14-4f2e-88fa-422a944e0cbe'	System	05 Aug 2020 23:04:24
User entered '99.5'	System	05 Aug 2020 23:04:24

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:06', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd375e7bf-4c14-4f2e-88fa-422a944e0cbe'	System	05 Aug 2020 23:04:24
User entered 'Yes (Y)'	System	05 Aug 2020 23:04:24

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient contacted and conmeds updated.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:51:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Heather Leary (b) (4)	06 Aug 2020 14:05:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:16', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd375e7bf-4c14-4f2e-88fa-422a944e0cbe'	System	05 Aug 2020 23:04:24
User entered '1'	System	05 Aug 2020 23:04:24

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:16', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd375e7bf-4c14-4f2e-88fa-422a944e0cbe' User entered '0'	System	05 Aug 2020 23:04:24

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd375e7bf-4c14-4f2e-88fa-422a944e0cbe'	System	05 Aug 2020 23:04:24
User entered '05 Aug 2020 18:04'	System	05 Aug 2020 23:04:24

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 4'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:32:15', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '73a3d7b7-65a2-4190-a272-2fa015f7339e'	System	07 Aug 2020 00:32:46
User entered 'Yes (Y)'	System	07 Aug 2020 00:32:46

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:32:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '73a3d7b7-65a2-4190-a272-2fa015f7339e'	System	07 Aug 2020 00:32:46
User entered '100.5'	System	07 Aug 2020 00:32:46

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:32:29', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '73a3d7b7-65a2-4190-a272-2fa015f7339e'	System	07 Aug 2020 00:32:46
User entered 'Yes (Y)'	System	07 Aug 2020 00:32:46

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient was contacted, and conmeds updated' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:51:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Heather Leary (b) (4)	07 Aug 2020 15:32:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:32:38', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '73a3d7b7-65a2-4190-a272-2fa015f7339e'	System	07 Aug 2020 00:32:46
User entered '1'	System	07 Aug 2020 00:32:46

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:32:38', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '73a3d7b7-65a2-4190-a272-2fa015f7339e'	System	07 Aug 2020 00:32:46
User entered '0'	System	07 Aug 2020 00:32:46

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:32:43', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '73a3d7b7-65a2-4190-a272-2fa015f7339e'	System	07 Aug 2020 00:32:46
User entered '06 Aug 2020 19:32'	System	07 Aug 2020 00:32:46

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 5'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:41:27', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f3ce7a23-2526-4201-86e2-c36eb6a977ce'	System	07 Aug 2020 22:41:55
User entered 'Yes (Y)'	System	07 Aug 2020 22:41:55

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:41:35', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f3ce7a23-2526-4201-86e2-c36eb6a977ce'	System	07 Aug 2020 22:41:55
User entered '100.4'	System	07 Aug 2020 22:41:55

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:41:42', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f3ce7a23-2526-4201-86e2-c36eb6a977ce'	System	07 Aug 2020 22:41:55
User entered 'Yes (Y)'	System	07 Aug 2020 22:41:55

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:51:52
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient contacted and concomitant medications updated' (Site from System).	Heather Leary (b) (4)	08 Aug 2020 14:13:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Aug 2020 22:41:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:41:49', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f3ce7a23-2526-4201-86e2-c36eb6a977ce'	System	07 Aug 2020 22:41:55
User entered '1'	System	07 Aug 2020 22:41:55

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:41:49', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f3ce7a23-2526-4201-86e2-c36eb6a977ce'	System	07 Aug 2020 22:41:55
User entered '0'	System	07 Aug 2020 22:41:55

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:41:54', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f3ce7a23-2526-4201-86e2-c36eb6a977ce' User entered '07 Aug 2020 17:41'	System	07 Aug 2020 22:41:55
	System	07 Aug 2020 22:41:55

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 6'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-08T18:05:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '04eb6214-45b3-42d7-b9c6-d12f55b88c1c'	System	09 Aug 2020 11:05:48
User entered 'Yes (Y)'	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-08T18:10:26', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '04eb6214-45b3-42d7-b9c6-d12f55b88c1c'	System	09 Aug 2020 11:05:48
User entered '98.5'	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:05:25', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '04eb6214-45b3-42d7-b9c6-d12f55b88c1c'	System	09 Aug 2020 11:05:48
User entered 'Yes (Y)'	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient contacted and conmeds updated' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:54:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:05:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '04eb6214-45b3-42d7-b9c6-d12f55b88c1c'	Heather Leary (b) (4)	09 Aug 2020 15:39:46
User entered '1'	System	09 Aug 2020 11:05:48
	System	09 Aug 2020 11:05:48
	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:05:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '04eb6214-45b3-42d7-b9c6-d12f55b88c1c' User entered '0'	System	09 Aug 2020 11:05:48
	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:05:46', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '04eb6214-45b3-42d7-b9c6-d12f55b88c1c'	System	09 Aug 2020 11:05:48
User entered '09 Aug 2020 06:05'	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 7'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:05:59', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9d076c5f-dd18-470d-8dd0-e7f1640fb675'	System	09 Aug 2020 23:08:40
User entered 'Yes (Y)'	System	09 Aug 2020 23:08:40

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:08:16', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9d076c5f-dd18-470d-8dd0-e7f1640fb675'	System	09 Aug 2020 23:08:40
User entered '99.3'	System	09 Aug 2020 23:08:40

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:08:29', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9d076c5f-dd18-470d-8dd0-e7f1640fb675'	System	09 Aug 2020 23:08:40
User entered 'No (N)'	System	09 Aug 2020 23:08:40

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:08:39', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9d076c5f-dd18-470d-8dd0-e7f1640fb675'	System	09 Aug 2020 23:08:40
User entered '09 Aug 2020 18:08'	System	09 Aug 2020 23:08:40

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:33:10', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '49482109-dd05-4a16-99d1-a214805b8394'	System	03 Aug 2020 22:33:55
User entered 'None (1)'	System	03 Aug 2020 22:33:55

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:33:15', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '49482109-dd05-4a16-99d1-a214805b8394'	System	03 Aug 2020 22:33:55
User entered 'No (N)'	System	03 Aug 2020 22:33:55

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:33:20', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '49482109-dd05-4a16-99d1-a214805b8394'	System	03 Aug 2020 22:33:55
User entered 'No (N)'	System	03 Aug 2020 22:33:55

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:33:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '49482109-dd05-4a16-99d1-a214805b8394'	System	03 Aug 2020 22:33:55
User entered 'None (1)'	System	03 Aug 2020 22:33:55

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:33:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '49482109-dd05-4a16-99d1-a214805b8394'	System	03 Aug 2020 22:33:55
User entered '03 Aug 2020 17:33'	System	03 Aug 2020 22:33:55

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 17:04'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 19:34'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:10:12', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3b45f339-6725-4dcb-8ef0-2a5b43111188'	System	04 Aug 2020 14:21:42
User entered 'Does not interfere with activity (2)'	System	04 Aug 2020 14:21:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:10:16', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3b45f339-6725-4dcb-8ef0-2a5b43111188'	System	04 Aug 2020 14:21:42
User entered 'No (N)'	System	04 Aug 2020 14:21:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:10:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3b45f339-6725-4dcb-8ef0-2a5b43111188'	System	04 Aug 2020 14:21:42
User entered 'Yes (Y)'	System	04 Aug 2020 14:21:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:21:14', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3b45f339-6725-4dcb-8ef0-2a5b43111188'	System	04 Aug 2020 14:21:42
User entered '8'	System	04 Aug 2020 14:21:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:21:21', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3b45f339-6725-4dcb-8ef0-2a5b43111188'	System	04 Aug 2020 14:21:42
User entered 'None (1)'	System	04 Aug 2020 14:21:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:21:40', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3b45f339-6725-4dcb-8ef0-2a5b43111188'	System	04 Aug 2020 14:21:42
User entered '04 Aug 2020 09:21'	System	04 Aug 2020 14:21:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 20:29'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 2'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:09:49', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '044be72d-db13-4a5e-9f5c-0c1baf057886'	System	05 Aug 2020 01:10:35
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 01:10:35

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:09:56', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '044be72d-db13-4a5e-9f5c-0c1baf057886'	System	05 Aug 2020 01:10:35
User entered 'No (N)'	System	05 Aug 2020 01:10:35

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:10:04', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '044be72d-db13-4a5e-9f5c-0c1baf057886'	System	05 Aug 2020 01:10:35
User entered 'No (N)'	System	05 Aug 2020 01:10:35

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:10:17', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '044be72d-db13-4a5e-9f5c-0c1baf057886'	System	05 Aug 2020 01:10:35
User entered 'None (1)'	System	05 Aug 2020 01:10:35

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:10:30', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '044be72d-db13-4a5e-9f5c-0c1baf057886'	System	05 Aug 2020 01:10:35
User entered '04 Aug 2020 20:10'	System	05 Aug 2020 01:10:35

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 3'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:30', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'eee1b1e9-27ba-410b-88df-e074d26683d2'	System	05 Aug 2020 23:04:50
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 23:04:50

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:34', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'eee1b1e9-27ba-410b-88df-e074d26683d2'	System	05 Aug 2020 23:04:50
User entered 'No (N)'	System	05 Aug 2020 23:04:50

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:39', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'eee1b1e9-27ba-410b-88df-e074d26683d2'	System	05 Aug 2020 23:04:50
User entered 'No (N)'	System	05 Aug 2020 23:04:50

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:43', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'eee1b1e9-27ba-410b-88df-e074d26683d2'	System	05 Aug 2020 23:04:50
User entered 'None (1)'	System	05 Aug 2020 23:04:50

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:48', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'eee1b1e9-27ba-410b-88df-e074d26683d2'	System	05 Aug 2020 23:04:50
User entered '05 Aug 2020 18:04'	System	05 Aug 2020 23:04:50

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 4'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:32:55', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd940b881-974f-467f-9f5c-fd305bf34c20'	System	07 Aug 2020 00:33:37
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 00:33:37

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:33:00', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd940b881-974f-467f-9f5c-fd305bf34c20'	System	07 Aug 2020 00:33:37
User entered 'No (N)'	System	07 Aug 2020 00:33:37

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:33:05', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd940b881-974f-467f-9f5c-fd305bf34c20'	System	07 Aug 2020 00:33:37
User entered 'No (N)'	System	07 Aug 2020 00:33:37

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:33:19', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd940b881-974f-467f-9f5c-fd305bf34c20'	System	07 Aug 2020 00:33:37
User entered 'None (1)'	System	07 Aug 2020 00:33:37

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:33:34', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd940b881-974f-467f-9f5c-fd305bf34c20'	System	07 Aug 2020 00:33:37
User entered '06 Aug 2020 19:33'	System	07 Aug 2020 00:33:37

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 5'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:42:18', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '57052115-f634-4a41-9c09-90e86ce9c934'	System	07 Aug 2020 22:43:01
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 22:43:01

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:42:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '57052115-f634-4a41-9c09-90e86ce9c934'	System	07 Aug 2020 22:43:01
User entered 'No (N)'	System	07 Aug 2020 22:43:01

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:42:26', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '57052115-f634-4a41-9c09-90e86ce9c934'	System	07 Aug 2020 22:43:01
User entered 'No (N)'	System	07 Aug 2020 22:43:01

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:42:32', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '57052115-f634-4a41-9c09-90e86ce9c934'	System	07 Aug 2020 22:43:01
User entered 'None (1)'	System	07 Aug 2020 22:43:01

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:42:57', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '57052115-f634-4a41-9c09-90e86ce9c934'	System	07 Aug 2020 22:43:01
User entered '07 Aug 2020 17:42'	System	07 Aug 2020 22:43:01

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 6'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:05:52', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '556f0bf3-d086-493b-9172-e7299c2204a8'	System	09 Aug 2020 11:06:15
User entered 'None (1)'	System	09 Aug 2020 11:06:15

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:05:56', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '556f0bf3-d086-493b-9172-e7299c2204a8'	System	09 Aug 2020 11:06:15
User entered 'No (N)'	System	09 Aug 2020 11:06:15

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:02', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '556f0bf3-d086-493b-9172-e7299c2204a8'	System	09 Aug 2020 11:06:15
User entered 'No (N)'	System	09 Aug 2020 11:06:15

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:07', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '556f0bf3-d086-493b-9172-e7299c2204a8'	System	09 Aug 2020 11:06:15
User entered 'None (1)'	System	09 Aug 2020 11:06:15

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:12', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '556f0bf3-d086-493b-9172-e7299c2204a8' User entered '09 Aug 2020 06:06'	System	09 Aug 2020 11:06:15
	System	09 Aug 2020 11:06:15

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 7'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:08:55', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f4689f9e-4084-4c6c-a202-e8e20d7aeedf'	System	09 Aug 2020 23:09:42
User entered 'None (1)'	System	09 Aug 2020 23:09:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:08:59', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f4689f9e-4084-4c6c-a202-e8e20d7aeedf'	System	09 Aug 2020 23:09:42
User entered 'No (N)'	System	09 Aug 2020 23:09:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:09:04', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f4689f9e-4084-4c6c-a202-e8e20d7aeedf'	System	09 Aug 2020 23:09:42
User entered 'No (N)'	System	09 Aug 2020 23:09:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:09:35', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f4689f9e-4084-4c6c-a202-e8e20d7aeedf'	System	09 Aug 2020 23:09:42
User entered 'None (1)'	System	09 Aug 2020 23:09:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:09:38', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'f4689f9e-4084-4c6c-a202-e8e20d7aeedf' User entered '09 Aug 2020 18:09'	System	09 Aug 2020 23:09:42
	System	09 Aug 2020 23:09:42

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:14', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff'	System	03 Aug 2020 22:34:47
User entered 'None (0)'	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:21', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff'	System	03 Aug 2020 22:34:47
User entered 'None (0)'	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:25', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff'	System	03 Aug 2020 22:34:47
User entered 'None (0)'	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:28', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff'	System	03 Aug 2020 22:34:47
User entered 'None (0)'	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:31', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff'	System	03 Aug 2020 22:34:47
User entered 'None (0)'	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:34', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff'	System	03 Aug 2020 22:34:47
User entered 'None (0)'	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff'	System	03 Aug 2020 22:34:47
User entered 'No (N)'	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-03T17:34:44', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '3a726943-e145-4171-a07b-ee7a0e2789ff' User entered '03 Aug 2020 17:34'	System	03 Aug 2020 22:34:47
	System	03 Aug 2020 22:34:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 17:04'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 19:34'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:21:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered 'None (0)'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:21:59', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered 'No interference with activity (1)'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:22:05', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered 'No interference with activity (1)'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:22:11', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered 'None (0)'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:22:14', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered 'None (0)'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:22:17', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered 'None (0)'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:22:26', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered 'No (N)'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T09:22:29', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5037f33a-cc5c-45fe-877c-61f50b480ce3'	System	04 Aug 2020 14:22:32
User entered '04 Aug 2020 09:22'	System	04 Aug 2020 14:22:32

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 20:29'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 2'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:10:38', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered 'No interference with activity (1)'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:10:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered 'No interference with activity (1)'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:10:59', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered 'No interference with activity (1)'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:11:07', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered 'None (0)'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:11:10', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered 'None (0)'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:11:13', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered 'No interference with activity (1)'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:11:34', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered 'No (N)'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-04T20:11:39', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'b7725dc3-2e8d-4af2-ae7d-046e35ca39f4'	System	05 Aug 2020 01:11:43
User entered '04 Aug 2020 20:11'	System	05 Aug 2020 01:11:43

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 3'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:04:53', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered 'None (0)'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:05:02', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered 'No interference with activity (1)'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:05:21', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered 'No interference with activity (1)'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:05:25', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered 'None (0)'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:05:28', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered 'None (0)'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:05:33', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered 'None (0)'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:05:55', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered 'No (N)'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-05T18:05:58', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '9be6ecf4-28a6-4d05-a3bc-3c0d95fba0ec'	System	05 Aug 2020 23:06:03
User entered '05 Aug 2020 18:05'	System	05 Aug 2020 23:06:03

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 4'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:33:43', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered 'None (0)'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:33:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered 'Some interference with activity (2)'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:33:58', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered 'No interference with activity (1)'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:34:06', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered 'None (0)'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:34:16', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:34:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered 'No interference with activity (1)'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:34:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered 'No (N)'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-06T19:36:42', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '662d7c56-fe8b-4eaf-b81e-ca02048c1757'	System	07 Aug 2020 00:36:47
User entered '06 Aug 2020 19:36'	System	07 Aug 2020 00:36:47

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 5'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:43:05', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d'	System	07 Aug 2020 22:44:08
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:43:13', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d'	System	07 Aug 2020 22:44:08
User entered 'Some interference with activity (2)'	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:43:19', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d'	System	07 Aug 2020 22:44:08
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:43:22', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d'	System	07 Aug 2020 22:44:08
User entered 'None (0)'	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:43:36', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d'	System	07 Aug 2020 22:44:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:43:42', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d'	System	07 Aug 2020 22:44:08
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:43:53', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d' User entered 'Yes (Y)'	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-07T17:44:06', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '8c457f71-9172-4766-b633-e0ed4260ce7d' User entered '07 Aug 2020 17:44'	System	07 Aug 2020 22:44:08
	System	07 Aug 2020 22:44:08

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 6'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:19', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e'	System	09 Aug 2020 11:07:13
User entered 'No interference with activity (1)'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:23', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e'	System	09 Aug 2020 11:07:13
User entered 'No interference with activity (1)'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:28', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e'	System	09 Aug 2020 11:07:13
User entered 'No interference with activity (1)'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:31', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e' User entered 'None (0)'	System	09 Aug 2020 11:07:13
	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:38', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e'	System	09 Aug 2020 11:07:13
User entered 'None (0)'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:06:44', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e'	System	09 Aug 2020 11:07:13
User entered 'None (0)'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:07:07', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e'	System	09 Aug 2020 11:07:13
User entered 'Yes (Y)'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T06:07:11', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '34fcae68-40e1-4544-add6-d74ac3ccc81e' User entered '09 Aug 2020 06:07'	System	09 Aug 2020 11:07:13
	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 7'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:10:34', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:10:58', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered 'Some interference with activity (2)'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:11:21', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:11:31', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered 'None (0)'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:11:37', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:11:48', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered 'None (0)'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:12:37', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered 'No (N)'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-09T18:12:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd601a666-2621-4ec4-8c4a-b712c95bc9ab'	System	09 Aug 2020 23:12:44
User entered '09 Aug 2020 18:12'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 11:07:13
User entered 'Day 8'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:12:44
User entered 'Day 9'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:06:58', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'fdddda49-f1b8-4266-9069-c293bd6f0fa7'	System	11 Aug 2020 17:07:06
User entered 'No interference with activity (1)'	System	11 Aug 2020 17:07:06

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:03', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'fdddda49-f1b8-4266-9069-c293bd6f0fa7'	System	11 Aug 2020 17:07:06
User entered '11 Aug 2020 12:07'	System	11 Aug 2020 17:07:06

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:07:06
User entered 'Day 10'	System	11 Aug 2020 17:07:06

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:55:32', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'e679f094-cc6f-4a52-9422-ef905d418317'	System	12 Aug 2020 23:55:37
User entered 'None (0)'	System	12 Aug 2020 23:55:37

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:55:35', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'e679f094-cc6f-4a52-9422-ef905d418317'	System	12 Aug 2020 23:55:37
User entered '12 Aug 2020 18:55'	System	12 Aug 2020 23:55:37

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:07:06

US3212016

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:07:06

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 11:07:13
User entered 'Day 8'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:12:44
User entered 'Day 9'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:16', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'ccf34fdb-1c87-4958-809c-bfd002b442e7'	System	11 Aug 2020 17:07:24
User entered 'Some interference with activity (2)'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:20', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'ccf34fdb-1c87-4958-809c-bfd002b442e7'	System	11 Aug 2020 17:07:24
User entered '11 Aug 2020 12:07'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:07:24
User entered 'Day 10'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:55:48', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '19abceaf-0f98-4852-ad89-af041b3242ae'	System	12 Aug 2020 23:55:53
User entered 'Some interference with activity (2)'	System	12 Aug 2020 23:55:53

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:55:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '19abceaf-0f98-4852-ad89-af041b3242ae'	System	12 Aug 2020 23:55:53
User entered '12 Aug 2020 18:55'	System	12 Aug 2020 23:55:53

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:07:24
User entered 'Day 11'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-14T06:19:05', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '6780da76-c38f-44a4-a505-b001f8943b7f'	System	14 Aug 2020 11:19:12
User entered 'None (0)'	System	14 Aug 2020 11:19:12

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:47:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-14T06:19:08', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '6780da76-c38f-44a4-a505-b001f8943b7f'	System	14 Aug 2020 11:19:12
User entered '14 Aug 2020 06:19'	System	14 Aug 2020 11:19:12

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 17:07:24

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 11:07:13
User entered 'Day 8'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 11:07:13

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:12:44
User entered 'Day 9'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:47:01

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:27', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '4d2c4a19-98b4-41ba-ab92-fd5517dea8a8'	System	11 Aug 2020 17:07:36
User entered 'No interference with activity (1)'	System	11 Aug 2020 17:07:36

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:31', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '4d2c4a19-98b4-41ba-ab92-fd5517dea8a8'	System	11 Aug 2020 17:07:36
User entered '11 Aug 2020 12:07'	System	11 Aug 2020 17:07:36

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:07:36
User entered 'Day 10'	System	11 Aug 2020 17:07:36

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:47:01

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:55:55', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '504edb7b-0af7-4bf8-8330-e11b643b08fb' User entered 'None (0)'	System	12 Aug 2020 23:56:03
	System	12 Aug 2020 23:56:03

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:55:59', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '504edb7b-0af7-4bf8-8330-e11b643b08fb' User entered '12 Aug 2020 18:55'	System	12 Aug 2020 23:56:03
	System	12 Aug 2020 23:56:03

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:07:36

US3212016

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:07:36

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:12:44
User entered 'Day 8'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:12:44
User entered 'Day 9'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:47:01

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:38', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '0b1e93cc-8d7b-473f-86b9-d10f67253d60'	System	11 Aug 2020 17:07:43
User entered 'None (0)'	System	11 Aug 2020 17:07:43

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '0b1e93cc-8d7b-473f-86b9-d10f67253d60'	System	11 Aug 2020 17:07:43
User entered '11 Aug 2020 12:07'	System	11 Aug 2020 17:07:43

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 11:05:48
User entered 'Day 8'	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 11:05:48

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Aug 2020 23:12:44
User entered 'Day 9'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:07:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '0f6a5c6b-d90b-4795-b8d0-226e5f3da7ad'	System	11 Aug 2020 17:08:05
User entered 'No (N)'	System	11 Aug 2020 17:08:05

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-11T12:08:00', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '0f6a5c6b-d90b-4795-b8d0-226e5f3da7ad'	System	11 Aug 2020 17:08:05
User entered '11 Aug 2020 12:08'	System	11 Aug 2020 17:08:05

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:12:44

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 17:07:06
User entered 'Day 10'	System	11 Aug 2020 17:07:06

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:56:03', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'e5f7106a-6422-48ee-95fb-e4f5f04fc900'	System	12 Aug 2020 23:56:09
User entered 'No (N)'	System	12 Aug 2020 23:56:09

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-08-12T18:56:06', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'e5f7106a-6422-48ee-95fb-e4f5f04fc900'	System	12 Aug 2020 23:56:09
User entered '12 Aug 2020 18:56'	System	12 Aug 2020 23:56:09

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 17:07:06

US3212016

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 10:47:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 17:07:06

US3212016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:13:42

US3212016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:13:42

US3212016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:13:42

US3212016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:13:42

US3212016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:13:46

US3212016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Aug 2020 20:13:46

US3212016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Aug 2020 20:14:22
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	18 Aug 2020 20:14:12
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:14:12

US3212016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:14:12

US3212016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Heather Leary (b) (4)	18 Aug 2020 20:14:22
User entered 'Contact Not Made (CONTACT NOT MADE)'	Heather Leary (b) (4)	18 Aug 2020 20:14:12

US3212016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Participant is in convalescent/illness period'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 20:14:12

US3212016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Sep 2020 17:07:24

US3212016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 17:07:24

US3212016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Reconciliation: Saliva sample collected on 20AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:09:54
Query 'Per GCL Reconciliation: Saliva sample collected on 20AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.'	Anna Pena (b) (4)	06 Nov 2020 15:42:14
answered with 'sample collected 20 AUG 2020 was collected for day 14 saliva sample' (Site from DM).	(b) (4)	
User opened query 'Per GCL Reconciliation: Saliva sample collected on 20AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:35:53
Query 'Per GCL Reconciliation: Swab sample collected on 20AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.'	(b) (4), (b) (6)	03 Nov 2020 07:35:39
canceled (Site from DM).		
User opened query 'Per GCL Reconciliation: Swab sample collected on 20AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.'	(b) (4), (b) (6)	03 Nov 2020 07:35:33
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:14:53
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	02 Sep 2020 17:07:54

US3212016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per source, visit was completed 25Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:43:42
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:43:37
Query 'Per source, visit was completed 25Aug20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 19:44:32
User entered '25 Aug 2020' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 19:44:24
User opened query 'Per source, visit was completed 25Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 20:14:51
User entered '24 Aug 2020'	Laura Ngansop Djampou (b) (4)	02 Sep 2020 17:07:54

US3212016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:14:55
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	02 Sep 2020 17:07:54

US3212016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:14:57
User entered empty.	Laura Ngansop Djampou	02 Sep 2020 17:07:54
	(b) (4)	

US3212016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:15:02
User entered 'Yes (Y)'	Laura Ngansop Djampou	02 Sep 2020 17:08:03
	(b) (4)	

US3212016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Sep 2020 17:08:03

US3212016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:18:39
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	17 Sep 2020 19:55:02
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 13:31:37
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:30:41

US3212016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 22:08:12
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'DATE IS CORRECT, SUBJECT TESTED POSITIVE FOR COVID19 AT BASELINE VISIT AND WAS IN ILLNESS VISITS/CONVALESCENT PERIOD' (Site from System).	Heather Leary (b) (4) (b) (4)	06 Nov 2020 20:44:06
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	06 Nov 2020 20:42:50
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:18:39
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 14:26:29
User entered '11 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 20:08:58
User entered '14 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 20:08:13
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Date confirmed - Out of window visit acknowledged.' (Site from System).	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 19:58:05
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	17 Sep 2020 19:55:02
User entered '11 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 19:55:02
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 13:31:37
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	14 Sep 2020 13:31:37
User entered empty; reason for change Data Entry Error	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:31:37
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 13:30:41

US3212016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:30:41

US3212016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:18:39
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou	14 Sep 2020 13:30:41
	(b) (4)	

US3212016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Sep 2020 13:30:41

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:58
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:13
User entered '11 Sep 2020'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered '17:48'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 17:48'	System	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered '98.3' F	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered '78'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered '12'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered '135'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered '87'	Laura Ngansop Djampou (b) (4)	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 13:42:00

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:20:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:33

US3212016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:21:41
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:24

US3212016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:21:41
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:09:14
User entered '11 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 20:09:14
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:58
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:13
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 19:55:02
User entered '14 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:24

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:35
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:35
User entered 'Confirmed COVID-19 (COVID)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:35
User entered empty.	System	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:47:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:47:48

US3212016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:58
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:59

US3212016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:58
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:09:30
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		17 Sep 2020 20:09:30
User entered '11 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	17 Sep 2020 20:09:30
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:58
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:13
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		17 Sep 2020 20:08:13
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 19:55:02
User entered '14 Sep 2020'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:59

US3212016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:22:58
User entered '18:13'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:47:59

US3212016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 18:13'	System	17 Sep 2020 20:09:30
User entered '14 Sep 2020 18:13'	System	14 Sep 2020 16:47:59

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:47:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:23:15
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:09:48
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		17 Sep 2020 20:09:48
User entered '11 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	17 Sep 2020 20:09:48
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:58
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 20:08:13
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		17 Sep 2020 20:08:13
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 19:55:02
User entered '14 Sep 2020'	Afifah Ayub (b) (4)	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:23:15
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:23:15
User entered '18:10'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:47:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 18:10'	System	17 Sep 2020 20:09:48
User entered '14 Sep 2020 18:10'	System	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:23:15
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:23:15
User entered empty.	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:47:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:48:10

US3212016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:23:25
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	14 Sep 2020 16:48:21

US3212016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:48:21

US3212016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:31:39
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:16:57

US3212016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per source, visit was completed on 10Sep20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 19:40:09
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:40:07
Query 'Per source, visit was completed on 10Sep20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 19:45:26
User entered '10 Sep 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 19:45:16
User opened query 'Per source, visit was completed on 10Sep20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 20:24:54
User entered '8 Sep 2020'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:16:57

US3212016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:31:41
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:16:57

US3212016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:31:43
User entered empty.	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:16:57

US3212016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:31:46
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:17:02

US3212016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 14:17:02

US3212016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:37:53
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:17:15

US3212016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:37:53
User entered '18 Sep 2020'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:17:15

US3212016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:37:53
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:17:15

US3212016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:37:53
User entered empty.	Laura Ngansop Djampou	21 Sep 2020 14:17:15
	(b) (4)	

US3212016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:40:45
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	21 Sep 2020 14:17:19

US3212016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 14:17:19

US3212016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:54:58
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 15:39:15

US3212016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:55:05
User entered '22 Sep 2020' reason for change: Data Entry Error	Laura Ngansop Djampou	01 Oct 2020 15:40:11
User entered '29 Sep 2020'	(b) (4)	
	Laura Ngansop Djampou	01 Oct 2020 15:39:15
	(b) (4)	

US3212016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:55:08
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 15:39:15

US3212016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:55:10
User entered empty.	Laura Ngansop Djampou	01 Oct 2020 15:39:15
	(b) (4)	

US3212016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 19:55:13
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	01 Oct 2020 15:39:20

US3212016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 15:39:20

US3212016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:10
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:34:55

US3212016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:10
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:34:55

US3212016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:10
User entered 'Clinic (Clinic)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:34:55

US3212016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	16 Oct 2020 21:34:55

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered '16:01'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:01'	System	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered '98.6' F	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered 'Oral (Oral)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered empty.	Laura Ngansop Djampou	16 Oct 2020 21:35:31
	(b) (4)	

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered '76'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered '15'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered '130'	Laura Ngansop Djampou	16 Oct 2020 21:35:31
	(b) (4)	

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:52
User entered '82'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 21:35:31

US3212016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:45:49
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:40

US3212016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:45:49
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:35:40

US3212016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:04
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:34:42

US3212016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:04
User entered '16 Oct 2020'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:34:42

US3212016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:04
User entered '16:14'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:34:42

US3212016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:47:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:14'	System	16 Oct 2020 21:34:42

US3212016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:46:12
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	16 Oct 2020 21:34:46

US3212016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 21:34:46

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 71'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-13T11:34:14', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '59ab0ed4-d370-4e2c-b2be-fbe3c5847a85' User entered 'No (N)'	System	13 Oct 2020 16:34:39
	System	13 Oct 2020 16:34:39

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Have you been exposed to someone with 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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-13T11:34:24', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '59ab0ed4-d370-4e2c-b2be-fbe3c5847a85'	System	13 Oct 2020 16:34:39
User entered 'No (N)'	System	13 Oct 2020 16:34:39

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-13T11:34:35', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '59ab0ed4-d370-4e2c-b2be-fbe3c5847a85' User entered '13 Oct 2020 11:34:35'	System	13 Oct 2020 16:34:39
	System	13 Oct 2020 16:34:39

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 78'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-20T09:44:06', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '26281b7d-7b64-4440-8ece-209dc83227b6'	System	20 Oct 2020 14:44:29
User entered 'No (N)'	System	20 Oct 2020 14:44:29

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Have you been exposed to someone with 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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-20T09:44:13', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '26281b7d-7b64-4440-8ece-209dc83227b6'	System	20 Oct 2020 14:44:29
User entered 'No (N)'	System	20 Oct 2020 14:44:29

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-20T09:44:27', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '26281b7d-7b64-4440-8ece-209dc83227b6' User entered '20 Oct 2020 09:44:27'	System	20 Oct 2020 14:44:29
	System	20 Oct 2020 14:44:29

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 92'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-31T17:05:47', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '91d36b1c-3d5f-41dd-8813-403b6bfa3217' User entered 'No (N)'	System	31 Oct 2020 22:06:03
	System	31 Oct 2020 22:06:03

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Have you been exposed to someone with 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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-31T17:05:55', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '91d36b1c-3d5f-41dd-8813-403b6bfa3217'	System	31 Oct 2020 22:06:03
User entered 'No (N)'	System	31 Oct 2020 22:06:03

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-10-31T17:06:00', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '91d36b1c-3d5f-41dd-8813-403b6bfa3217' User entered '31 Oct 2020 17:06:00'	System	31 Oct 2020 22:06:03
	System	31 Oct 2020 22:06:03

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 99'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-11T09:31:17', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5d18ebe1-64a5-4e97-9117-6df8286aec0e'	System	11 Nov 2020 15:32:05
User entered 'No (N)'	System	11 Nov 2020 15:32:05

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Have you been exposed to someone with 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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-11T09:31:32', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5d18ebe1-64a5-4e97-9117-6df8286aec0e' User entered 'Yes (Y)'	System	11 Nov 2020 15:32:05
	System	11 Nov 2020 15:32:05

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Please 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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-11T09:31:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5d18ebe1-64a5-4e97-9117-6df8286aec0e'	System	11 Nov 2020 15:32:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 15:32:05

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-11T09:31:56', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '5d18ebe1-64a5-4e97-9117-6df8286aec0e' User entered '11 Nov 2020 09:31:56'	System	11 Nov 2020 15:32:05
	System	11 Nov 2020 15:32:05

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered 'Day 106'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-16T12:00:16', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '2c51fab9-1992-48f0-86a8-b5c8a624dd76'	System	16 Nov 2020 18:00:34
User entered 'No (N)'	System	16 Nov 2020 18:00:34

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Have you been exposed to someone with 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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-16T12:00:28', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '2c51fab9-1992-48f0-86a8-b5c8a624dd76'	System	16 Nov 2020 18:00:34
User entered 'No (N)'	System	16 Nov 2020 18:00:34

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-16T12:00:31', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: '2c51fab9-1992-48f0-86a8-b5c8a624dd76' User entered '16 Nov 2020 12:00:31'	System	16 Nov 2020 18:00:34
	System	16 Nov 2020 18:00:34

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 22:01:09

US3212016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Aug 2020 22:01:09
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 22:01:09

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '30 Sep 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '04 Oct 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-20T18:24:41', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd2aa7755-9ac2-4dbc-affa-b03a676f85a4' User entered 'No (N)'	System	21 Nov 2020 00:24:59
	System	21 Nov 2020 00:24:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

Have you been exposed to someone with 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 (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-20T18:24:46', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd2aa7755-9ac2-4dbc-affa-b03a676f85a4' User entered 'No (N)'	System	21 Nov 2020 00:24:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A7F08191-C33F-49BE-BE1F-8137368AA965)', Time: '2020-11-20T18:24:51', User OID: 'PatientReportedOutcome (US3212016)', ODM File OID: 'd2aa7755-9ac2-4dbc-affa-b03a676f85a4' User entered '20 Nov 2020 18:24:51'	System	21 Nov 2020 00:24:59

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 12:07:49

US3212016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:47:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:07:49
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 12:07:49

US3212016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:52
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:23:50

US3212016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:52
User entered '23 Oct 2020'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:23:50

US3212016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:52
User entered 'Contact Made (CONTACT MADE)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:23:50

US3212016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:47:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:52
User entered empty.	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:23:50

US3212016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:35:58
User entered 'Yes (Y)'	Laura Ngansop Djampou (b) (4)	26 Oct 2020 17:23:57

US3212016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:47:01

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 17:23:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:47:01

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:09:03
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:45:54
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:37:47
User entered '7 Aug 2020'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:17:06

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:47:01

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:09:09
User entered '16:49' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 18:59:25
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:46:00
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:37:51
User entered '16:00'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:17:06

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:47:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Aug 2020 16:49'	System	24 Sep 2020 18:59:25
User entered '7 Aug 2020 16:00'	System	11 Aug 2020 13:17:06

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:47:01

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:09:00
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:45:57
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:37:51
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:17:06

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:47:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:10:44
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:45:59
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:37:51
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:17:06

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4)	24 Sep 2020 19:02:02
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	13 Aug 2020 14:48:09
User entered 'Day 4 (Day 4)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

Date

Audit	User	Time (GMT)
User closed query 'If symptoms began on 04Aug20. Please complete symptom log pages for 05-07Aug20 even if Telemedicine call not completed on those days.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:53
Query 'If symptoms began on 04Aug20. Please complete symptom log pages for 05-07Aug20 even if Telemedicine call not completed on those days.' answered with 'will update' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:40:50
User opened query 'If symptoms began on 04Aug20. Please complete symptom log pages for 05-07Aug20 even if Telemedicine call not completed on those days.' (Site from CRA).	Afifah Ayub (b) (4)	28 Oct 2020 21:22:00
Query 'Per source, Subject was seen in clinic for Illness visit on 07Aug20. Please verify and update accordingly.' canceled (Site from CRA).	(b) (4)	
User opened query 'Per source, Subject was seen in clinic for Illness visit on 07Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 18:48:39
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 18:47:28
User entered '04 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:42:45
User closed query 'Please confirm if date of call was 06Aug20 or 07Aug20. Dates entered are conflicting for this assessment. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 17:23:32
DataPoint Verified.	Afifah Ayub (b) (4)	13 Oct 2020 17:23:32
Query 'Please confirm if date of call was 06Aug20 or 07Aug20. Dates entered are conflicting for this assessment. Please verify and update accordingly.' answered with 'Data entry error' (Site from CRA).	(b) (4)	
User entered '7 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 18:45:52
User opened query 'Please confirm if date of call was 06Aug20 or 07Aug20. Dates entered are conflicting for this assessment. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:45:45
User entered '6 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 14:48:19
	Heather Leary (b) (4)	13 Aug 2020 14:48:09
	(b) (4)	
	Heather Leary (b) (4)	12 Aug 2020 21:26:59
	(b) (4), (b) (6)	
	Heather Leary (b) (4)	11 Aug 2020 13:20:16
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:45:55
User entered '0'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	afifah Ayub (b) (4)	03 Nov 2020 17:51:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 21:11:14
User entered '97'	Heather Leary (b) (4)	11 Aug 2020 13:20:16
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 18:48:09
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:46:14
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 21:27:38
User entered '100.5' F	Heather Leary (b) (4)	11 Aug 2020 13:20:16
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Sep 2020 21:13:27
User entered 'None (None)'	Heather Leary (b) (4)	11 Aug 2020 13:20:16
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:13:32
User entered 'Mild (Mild)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:13:34
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

Fatigue

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:53:13
User entered 'None (None)'	Heather Leary (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:53:13
User entered 'None (None)'	Heather Leary (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:53:13
User entered 'None (None)'	Heather Leary (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:53:13
User entered 'None (None)'	Heather Leary (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:53:13
User entered 'None (None)'	Heather Leary (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:53:13
User entered 'None (None)'	Heather Leary (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:16

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:57
User entered '8 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:59
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:47:23
User entered '97'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:48:54
User entered '98.5' F	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:31:23
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:49:33
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:49:38
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:30:51
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:49:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:27:21
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:50:18
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:27:21
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:51:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:50:31
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:50:37
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:50:48
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:52:09
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:27:21
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:52:11
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:27:21
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:52:22
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:27:21
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:52:31
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:27:21
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:52:36
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:31:14
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37
User entered 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:33:21
User entered '9 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:33:44
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:33:42
User entered '98'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:33:39
User entered '98.7' F	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:36:09
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:34:38
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:34:43
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:36:12
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:08
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:16
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:21
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:28
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:36
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:37
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:48
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:52
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:35:56
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
User closed query 'Per source, subject experienced mild diarrhea. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:36:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:36:20
Query 'Per source, subject experienced mild diarrhea. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	28 Oct 2020 21:19:55
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	28 Oct 2020 21:19:45
User opened query 'Per source, subject experienced mild diarrhea. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 20:36:48
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:28:56
User entered 'Mild (Mild)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:36:23
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37
User entered 'Day 4 (Day 4)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:43:24
User entered '10 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:43:36
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:43:38
User entered '98'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:43:40
User entered '98.7' F	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:54:14
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:43:57
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:44:05
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:54:16
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:44:15
User entered 'Moderate (Moderate)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:44:23
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
User closed query 'Per source, subject experienced mild body aches. Please verify and update accordingly.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:53:25
	(b) (4), (b) (6)	29 Oct 2020 14:53:23
Query 'Per source, subject experienced mild body aches. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	29 Oct 2020 14:22:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	29 Oct 2020 14:22:11
User opened query 'Per source, subject experienced mild body aches. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 21:46:47
User entered 'None (None)'	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:46:57
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:07
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:11
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:15
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:17
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:26
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:47:53
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:48:19
User entered 'Mild (Mild)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:54:21
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:54:26
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:33:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:33:31
User entered '11 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:05
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:28
User entered '97' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 15:33:31
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:27
User entered '98.7' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:31
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:50
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:52
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:57:58
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	(b) (4)	
	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:20
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:22
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:34
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:37
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:43
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 14:58:46
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	13 Oct 2020 17:30:46
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:02:11
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:33:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:17:02
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:42:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:42:30
User entered '12 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:18:52
User entered '97' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 15:42:30
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:02
User entered '98.7' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:15
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:24
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:35
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:37
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:47
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:48
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:52
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:19:58
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:20:01
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:20:04
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'Day 7 (Day 7)' reason for change:	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
Data Entry Error	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:20:50
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:44:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:44:23
User entered '13 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:20:52
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:21:40
User entered '97' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 15:44:23
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:21:57
User entered '98.7' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:22:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:22:41
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:22:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:22:55
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:22:57
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:05
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:08
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:10
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:16
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:18
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:23
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:24
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:23:28
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:44:23
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change:	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'Day 8 (Day 8)' reason for change:	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
Data Entry Error	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:24:47
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:46:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:46:25
User entered '14 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:24:49
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:26:01
User entered '97' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 15:46:25
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:26:03
User entered '98.6' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:28:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:28:20
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:29:50
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:29:53
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:29:57
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:01
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:03
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:14
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:15
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:18
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:20
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:23
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:46:25
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change:	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)' reason for change:	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
Data Entry Error	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:42
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:59:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:59:27
User entered '15 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:30:45
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:31:47
User entered '98' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 15:59:27
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:31:01
User entered '98.7' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:31:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:31:55
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	(b) (4)	
	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:06
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:08
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:12
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:16
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:19
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:23
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:27
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:37
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:40
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:32:44
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 15:42:30
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:33:01
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 15:59:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 15:59:27
User entered '16 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:33:02
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:33:26
User entered '98' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 15:59:27
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:33:17
User entered '98.7' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:36
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:42
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	(b) (4)	
	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:46
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:48
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:51
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:56
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:34:58
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:35:08
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:35:13
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:35:26
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:35:27
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

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Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:35:30
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 15:59:27
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change:	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'Day 11 (Day 11)' reason for change:	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
Data Entry Error	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:36:06
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:02:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:02:44
User entered '17 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:36:32
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:36:30
User entered '98' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 16:02:44
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:36:18
User entered '98.7' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:27
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:11
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:42
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:43
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:48
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:51
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:53
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:57
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:39:58
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:37
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:39
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:44
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:40:46
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:02:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)' reason for change:	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'Day 12 (Day 12)' reason for change:	Afifah Ayub (b) (4)	30 Sep 2020 15:42:30
Data Entry Error	(b) (4)	
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:46:46
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:04:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:04:31
User entered '18 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:49:44
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:46:48
User entered '0'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:47:11
User entered '99' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 16:04:31
User entered empty.	System	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:47:02
User entered '98.6' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:47:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:47:54
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:38
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:03
User entered 'Mild (Mild)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:13
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:15
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:18
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:22
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:23
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:31
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:33
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:45
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:47
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:51
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:48:55
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:04:31
User entered empty.	Afifah Ayub (b) (4)	29 Sep 2020 21:49:44

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)' reason for change:	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'Day 13 (Day 13)'	Afifah Ayub (b) (4)	30 Sep 2020 16:06:48
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 15:59:02
User entered '19 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:38
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:06
User entered '98'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:00:59
User entered '98.6' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:20
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:24
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:02:18
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:32
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:36
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:41
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:43
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:46
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:48
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:52
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:01:54
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:02:00
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:02:01
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:02:04
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:02:08
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:06:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)' reason for change:	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
Data Entry Error	(b) (4)	
User entered 'Day 14 (Day 14)'	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:04:23
User entered '20 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:04:26
User entered '0'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:04:27
User entered '99'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.7' F	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:09
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:11
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:13
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:16
User entered 'None (None)'	Afifah Ayub (b) (4) (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:17
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:24
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:27
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:30
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:32
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:38
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:06:40
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:07:05
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:07:07
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:07:10
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:07:15
User entered 'None (None)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 16:08:33
User entered empty.	Afifah Ayub (b) (4)	30 Sep 2020 16:07:49

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:05
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 21:24:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 21:24:37
User entered '05 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 21:22:27
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:07
User entered '1' reason for change: Data Entry Error	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:09
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:11
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:13
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:14
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:15
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:18
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:19
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:21
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:22
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:23
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:25
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:26
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:31
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:32
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:34
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:40:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:27

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:39
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 21:24:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 21:24:37
User entered '06 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 21:22:42
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:41
User entered '1' reason for change: Data Entry Error	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
User entered '0'	Afifah Ayub (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:44
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:45
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:46
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:48
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:49
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:50
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:53
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:54
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:56
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:57
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:58
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:42:00
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:42:01
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:42:03
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:42:04
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:42:06
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:42:07
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:22:42

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:05
User entered '07 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:55:22
DataPoint Un-verified.	(b) (4)	
	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 21:41:06
User entered '1'	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
User entered '97' reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:08
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	03 Nov 2020 17:51:09
User entered empty.	System	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
User entered '100.5' F reason for change: Data Entry Error	Afifah Ayub (b) (4)	03 Nov 2020 17:51:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:10
User entered empty.	Afifah Ayub (b) (4)	28 Oct 2020 21:24:37
	(b) (4)	

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:13
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:16
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:17
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:19
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:21
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:22
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:24
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:25
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:27
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:28
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:29
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:31
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:32
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:33
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:47:01

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 21:41:35
User entered empty.	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:24:37

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab Sample dated 07Aug2020 is recorded under Illness visit in EDC, however a sample is reported under Illness visit dated 09Aug2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:50:18
Query 'Per GCL Lab Reconciliation: Swab Sample dated 07Aug2020 is recorded under Illness visit in EDC, however a sample is reported under Illness visit dated 09Aug2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'The data entered is correct.' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	28 Oct 2020 21:13:50
User opened query 'Per GCL Lab Reconciliation: Swab Sample dated 07Aug2020 is recorded under Illness visit in EDC, however a sample is reported under Illness visit dated 09Aug2020 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 15:26:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:01
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:38:25
User entered '7 Aug 2020'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:03
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:38:58
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:32:11
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:27
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:24
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:06
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:39:01
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE form updated' (Site from System).	Heather Leary (b) (4) (b) (4)	12 Aug 2020 14:22:18
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	11 Aug 2020 13:20:48
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[Date of Test](#)

Audit	User	Time (GMT)
Query 'Per GCL Reconciliation: Swab sample collected on 20AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' canceled (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:35:04
User opened query 'Per GCL Reconciliation: Swab sample collected on 20AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:34:52
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:42:58
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:09
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:39:06
User entered '3 Aug 2020'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

Type of Test Performed

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:11
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:40:51
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:12
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:41:01
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 14:15:13
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:14
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:41:06
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:16
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:41:08
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:20:48

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:47:01

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:50:43
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:28:45
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:23
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:43:35
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:28:47
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:28:48
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:28:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 14:16:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:36
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:43:37
User entered '18'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:28:56
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:37
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:43:39
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:00
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:01
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 14:16:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:40
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:43:58
User entered '68'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:04
User closed query 'Per DM: Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level? is recorded as Yes but saturation is recorded as 97%. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	14 Aug 2020 16:12:04
Query 'Per DM: Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level? is recorded as Yes but saturation is recorded as 97%. Please review and reconcile.' answered with 'Data entry error' (Site from DM).	Heather Leary (b) (4)	13 Aug 2020 14:41:51
User entered 'No (N)' reason for change: Data Entry Error	Heather Leary (b) (4)	13 Aug 2020 14:41:42
User opened query 'Per DM: Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level? is recorded as Yes but saturation is recorded as 97%. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Aug 2020 09:13:52
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:42
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:43:42
User entered 'Yes (Y)'	Heather Leary (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:10
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:14
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 14:16:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:45
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:47:37
User entered '97'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:18
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:55
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:47:48
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:25
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:28
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:50:39

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:27
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:47:59
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:17
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:15
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:19
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:26
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:22
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:38
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 14:16:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 14:16:28
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:47:01

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:48:45
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:21:57

US3212016

Folder: Covid-19 Assessment 07 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:47:01

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:29:49
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	30 Sep 2020 20:20:57
DataPoint Un-verified.	(b) (4), (b) (6)	12 Aug 2020 21:48:09
DataPoint Verified.	(b) (4), (b) (6)	12 Aug 2020 20:49:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Aug 2020 00:01:18

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:47:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:47:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:49:41
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:49:43
User entered '9 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:47:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:47:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:52:00
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:52:02
User entered '11 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:47:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:47:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:58:47
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:58:49
User entered '13 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:47:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:47:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:01:53
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:01:54
User entered '15 Aug 2020'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:47:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:47:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 21:05:52
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per source, visit was completed 20Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:43:24
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:43:19
Query 'Per source, visit was completed 20Aug20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 16:49:10
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 16:49:05
User opened query 'Per source, visit was completed 20Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 21:05:50
User entered '17 Aug 2020'	Heather Leary (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:47:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:47:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:34:14
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:55:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 16:55:20
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	25 Sep 2020 16:55:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Aug 2020 19:11:42
	Heather Leary (b) (4)	18 Aug 2020 19:11:42
	(b) (4)	

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:34:15
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:47:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:47:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:34:18
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:55:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 16:55:20
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	25 Sep 2020 16:55:20
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 19:11:42
User entered empty.	Heather Leary (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:34:20
User entered empty.	Heather Leary (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:54:28
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "subject seen for Covid D1 on 07AUG2020 after testing positive at screening", and swab sample collected on 07AUG2020 is present in EDC. Kindly confirm if swab sample was collected or not on 20AUG2020 at illness visit to be updated in GCL records, and if collected, please update in EDC as appropriate.' answered with 'Illness Visit swab collected on 20AUG2020 is shown in PPD lab portal. ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	24 Nov 2020 14:55:13
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "subject seen for Covid D1 on 07AUG2020 after testing positive at screening", and swab sample collected on 07AUG2020 is present in EDC. Kindly confirm if swab sample was collected or not on 20AUG2020 at illness visit to be updated in GCL records, and if collected, please update in EDC as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	24 Nov 2020 05:33:21
User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 20AUG2020 is reported under Illness D3-D21 visit in PPD Central lab, however the same is missing in EDC. Please confirm if visit is performed on 20AUG2020, if yes sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4)	24 Nov 2020 05:33:21
Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 20AUG2020 is reported under Illness D3-D21 visit in PPD Central lab, however the same is missing in EDC. Please confirm if visit is performed on 20AUG2020, if yes sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'subject seen for Covid D1 on 07AUG2020 after testing positive at screening ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	23 Nov 2020 21:58:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 20AUG2020 is reported under Illness D3-D21 visit in PPD Central lab, however the same is missing in EDC. Please confirm if visit is performed on 20AUG2020, if yes sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 08:07:37
	Afifah Ayub (b) (4)	10 Nov 2020 14:04:00
	(b) (4)	
User entered '07 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	10 Nov 2020 14:04:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:54:28
User entered '7 Aug 2020'	Heather Leary (b) (4)	17 Aug 2020 22:09:55
	(b) (4)	

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:54:28
User entered 'Clinic (Clinic)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:28
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:30
User entered '7 Aug 2020'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:32
User entered '16:45'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered '7 Aug 2020 16:45'	System	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:33
User entered '67' in reason for change: Data Entry Error	Heather Leary (b) (4)	18 Aug 2020 18:59:55
User entered missing code ND - Not Done.	(b) (4)	
	Heather Leary (b) (4)	17 Aug 2020 22:10:41
	(b) (4)	
DataPoint set to visible.	System	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:34
User entered '240' lb reason for change: Data Entry Error	Heather Leary (b) (4)	18 Aug 2020 18:59:55
User entered missing code ND - Not Done.	(b) (4)	
	Heather Leary (b) (4)	17 Aug 2020 22:10:41
DataPoint set to visible.	(b) (4)	
	System	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:36
User entered '100.5' F	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:37
User entered 'Oral (Oral)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:38
User entered empty.	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:40
User entered '68'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:42
User entered '18'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per source systolic pressure is 128. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 18:59:29
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 18:59:26
Query 'Per source systolic pressure is 128. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Heather Leary (b) (4) (b) (4)	31 Aug 2020 14:21:09
User entered '128' reason for change: Data Entry Error	Heather Leary (b) (4) (b) (4)	31 Aug 2020 14:21:03
User opened query 'Per source systolic pressure is 128. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	28 Aug 2020 21:55:19
User entered '120'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:44
User entered '88'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:10:41

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Per source, PE was completed. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 02:19:52
Query 'Per source, PE was completed. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4) (b) (4)	29 Oct 2020 16:42:15
User opened query 'Per source, PE was completed. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:14:20
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 15:48:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:48:12
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:59
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:11:21

US3212016

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 15:48:12
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:48:12
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:55:59
User entered empty.	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:11:21

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 15:41:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:41:19
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:56:07
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:11:32

US3212016

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 15:41:19
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:41:19
DataPoint Verified.	(b) (4), (b) (6)	28 Aug 2020 21:56:07
User entered empty.	Heather Leary (b) (4) (b) (4)	17 Aug 2020 22:11:32

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	17 Aug 2020 22:09:55

US3212016

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint set to visible.	System	17 Aug 2020 22:09:55

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:57
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	29 Sep 2020 17:03:39
User entered 'Yes (Y)'	Afifah Ayub (b) (4)	29 Sep 2020 16:57:15

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:57
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	29 Sep 2020 17:03:39
User entered '11 Sep 2020'	Afifah Ayub (b) (4)	29 Sep 2020 16:57:15

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:57
User entered empty; reason for change Data Entry Error	Afifah Ayub (b) (4)	29 Sep 2020 17:03:39
User entered 'Clinic (Clinic)'	Afifah Ayub (b) (4)	29 Sep 2020 16:57:15

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:47:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	29 Sep 2020 16:57:15

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:42
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:47:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 17:03:47

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:49
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:54

US3212016

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:47:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:47:49
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:03:54

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:48:06
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:02

US3212016

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:47:01

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 20:48:06
User entered empty.	Afifah Ayub (b) (4) (b) (4)	29 Sep 2020 17:04:02

US3212016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:47:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:04:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Heather Leary (b) (4)	12 Aug 2020 14:19:17
User entered 'No (N)'	Heather Leary (b) (4)	05 Aug 2020 14:02:22

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:35
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 15:59:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	26 Oct 2020 15:59:39
Data point term sent to Coder	System	26 Oct 2020 15:29:13
User entered 'Worsening Hypertension'	Reagan Reed (b) (4)	26 Oct 2020 15:28:23
	(b) (4)	

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:38
User entered 'Yes (Y)'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:54
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 15:28:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 15:28:32
User entered 'No (N)' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Oct 2020 15:28:32
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 15:28:23
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:56
User entered '10 Aug 2020'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:42:57
User entered empty.	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:17:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:17:46
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:00
User entered 'No (N)'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Nov 2020 14:17:55
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	06 Nov 2020 14:17:55
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Nov 2020 14:17:46
DataPoint Un-verified.	Reagan Reed (b) (4)	06 Nov 2020 14:17:46
User entered empty; reason for change Data Entry Error	(b) (4)	
DataPoint Verified.	Reagan Reed (b) (4)	06 Nov 2020 14:17:46
	(b) (4)	
	(b) (4), (b) (6)	29 Oct 2020 16:43:10
User entered '11 Sep 2020'	(b) (4), (b) (6)	
	Reagan Reed (b) (4)	26 Oct 2020 15:28:23
	(b) (4)	

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:12
User entered empty.	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

Severity

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:57:44
Query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' answered with 'updated ' (Site from DM).	Reagan Reed (b) (4) (b) (4)	13 Nov 2020 19:30:12
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	13 Nov 2020 19:30:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	13 Nov 2020 19:30:06
User opened query 'Per DM CLR: Please verify the severity as a Worsening of the Med History condition would be expected to be > Grade of MH. Please confirm/update the severity or remove if a duplicate from baseline medical history. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:05:10
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:14
User entered 'Grade 1/Mild (Grade 1/Mild)'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:16
User entered 'No (N)'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:23
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:25
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:26
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:28
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:28:23
	(b) (4)	

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:30
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:28:23
	(b) (4)	

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:32
User entered empty.	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:33
User entered empty.	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:35
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:36
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:38
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 15:28:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 15:28:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Reagan Reed (b) (4)	26 Oct 2020 15:28:48
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 15:28:23
User entered empty.	Reagan Reed (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:53
User entered 'Not Applicable (NOT APPLICABLE)'	Reagan Reed (b) (4)	26 Oct 2020 15:28:23
	(b) (4)	

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:44:00
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:43:58
User entered '1'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:44:02
User entered '0'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:17:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:17:55
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:44:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:44:06
User entered empty.	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:44:08
User entered empty.	Reagan Reed (b) (4) (b) (4)	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 15:28:23

US3212016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:47:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Oct 2020 15:28:23

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:47:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:44:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:43:58

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:46:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:46:04
Data point term sent to Coder	System	03 Aug 2020 21:45:49
User entered 'Omeprazole'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:07:12
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:07:10
Query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:47:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 17:47:17
User opened query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:31:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:04
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:08
User entered '20'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:06
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:42
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:43
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:02:47
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'updated' (Site from DM).	Asifah Ayub (b) (4)	23 Sep 2020 17:41:51
User entered 'once daily (QD)' reason for change:	Asifah Ayub (b) (4)	23 Sep 2020 17:41:43
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:35:35
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:46
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:51
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:37:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 22:01:09
User entered 'UN UNK 2020'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:56
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:32:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:46:52
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:33:03
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		03 Aug 2020 21:46:52
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		03 Aug 2020 21:45:47
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:33:04
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:46:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Aug 2020 21:46:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:46:52
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Aug 2020 21:45:47
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:41:43
User entered empty.	System	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:41:43
User entered empty.	System	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:41:43
User entered empty.	System	03 Aug 2020 21:45:47

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:33:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:05:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 04:05:14
Data point term sent to Coder	System	03 Aug 2020 21:49:51
User entered 'Symbicort (Budesonide/Formoterol Fumarate)'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:07:21
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:07:19
Query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:48:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 17:48:18
User opened query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:34:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:34:33
User entered 'Asthma'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per source, administration is 80/4.5, please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:07:30
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:07:27
Query 'Per source, administration is 80/4.5, please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:48:34
User entered '80/4.5' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 17:48:18
User opened query 'Per source, administration is 80/4.5, please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:35:12
User entered '80/40.5'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:35:16
User entered 'ug (ug)'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:35:18
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:35:19
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:35:20
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:35:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:35:25
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per source, start date is UNK 2016. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:07:38
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:07:36
Query 'Per source, start date is UNK 2016. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:48:42
User entered 'UN UNK 2016' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:48:18
User opened query 'Per source, start date is UNK 2016. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:36:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:37:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 22:01:09
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 21:52:36
User entered 'UN UNK 1995' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Aug 2020 21:52:36
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	03 Aug 2020 21:49:07
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:06
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:10
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:11
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Aug 2020 21:49:07

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 11:47:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 11:47:20
Data point term sent to Coder	System	03 Aug 2020 21:50:55
User entered 'Ventolin (Albuterol)'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:07:45
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:07:43
Query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:49:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 17:49:06
User opened query 'Per source, this medication is not taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:36:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:44
User entered 'Asthma'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:45
User entered '180'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:47
User entered 'ug (ug)'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:49
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:50
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:58
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:54
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:52
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:36:56
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:37:01
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:37:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Aug 2020 23:37:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 22:01:09
User entered 'UN UNK 1995'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:37:06
User entered '0'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:37:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:37:10
User entered empty.	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:37:11
User entered 'No (N)'	(b) (4), (b) (6)	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Aug 2020 21:50:44

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 14:24:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 14:24:37
Data point term sent to Coder Coding entries removed.	System Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:07:47 06 Nov 2020 14:07:45
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 14:09:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 14:09:16
Data point term sent to Coder User entered 'Ibuprofen'	System Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:08:09 05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:04
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Reagan Reed (b) (4)	06 Nov 2020 14:07:45
	(b) (4)	
User entered 'Covid-19' reason for change: Data Entry Error	Reagan Reed (b) (4)	06 Nov 2020 14:07:45
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:54:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' answered with 'Associated with AE #1' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	14 Oct 2020 17:47:24

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 09:42:18
	(b) (4), (b) (6)	01 Oct 2020 15:44:07
User entered 'Fever'	Afifah Ayub (b) (4)	05 Aug 2020 14:07:53
	(b) (4)	

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:09
User entered '600'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:10
User entered 'mg (mg)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:12
User entered empty.	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:13
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	14 Sep 2020 16:38:56
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	14 Sep 2020 16:38:56
User entered 'as needed (PRN)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Sep 2020 16:38:56
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
User entered 'once (ONCE)'	System	14 Sep 2020 16:38:43
	Afifah Ayub (b) (4)	05 Aug 2020 14:07:53
	(b) (4)	

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:15
User entered empty.	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:17
User entered 'Oral (ORAL)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:19
User entered empty.	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:22
User entered '4 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:24
User entered '0'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:26
User entered 'No (N)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:29
User entered '10 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	14 Sep 2020 16:38:43
User entered '4 Aug 2020'	Afifah Ayub (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:54:32
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' answered with 'Associated with COVID-19 adverse event.' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	05 Oct 2020 16:16:09
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:44:47
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:44:31

v6.020 DTW (1102)

2150 of 2307

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Afifah Ayub (b) (4) (b) (4)	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 14:07:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 14:06:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 14:06:37
Data point term sent to Coder Coding entries removed.	System Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:05:45 06 Nov 2020 14:04:59
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 14:39:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 14:39:42
Data point term sent to Coder User entered 'Mucinex'	System Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:39:12 08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:32
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:51:52
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	06 Nov 2020 14:05:09
DataPoint Un-verified.	(b) (4)	
User entered 'Covid-19' reason for change: Data Entry Error	Reagan Reed (b) (4)	06 Nov 2020 14:04:59
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:36:31
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:34
User entered 'Nasal congestion'	Heather Leary (b) (4)	08 Aug 2020 14:38:36
	(b) (4)	

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:39
User entered '600'	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:42
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:45
User entered empty.	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:47
User entered 'as needed (PRN)' reason for change:	Heather Leary (b) (4)	08 Aug 2020 14:39:31
Data Entry Error	(b) (4)	
User entered 'every month (QM)'	Heather Leary (b) (4)	08 Aug 2020 14:38:36
	(b) (4)	

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:48
User entered empty.	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:51
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:53
User entered empty.	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Afifah Ayub (b) (4)	01 Oct 2020 17:49:53
	(b) (4)	
User entered '06 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:49:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:45:55
User entered '6 Aug 2020'	Heather Leary (b) (4)	08 Aug 2020 14:38:36
	(b) (4)	

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:46:00
User entered '0'	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source, medication stop date is 11Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:08:08
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:08:06
Query 'Per source, medication stop date is 11Aug20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:50:01
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:49:53
User opened query 'Per source, medication stop date is 11Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:46:31
User entered 'Yes (Y)'	Heather Leary (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:08:11
User entered '11 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:49:53
User entered empty.	Heather Leary (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:46:37
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 14:39:31
User entered '1'	System	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 14:39:31
User entered '1'	System	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 14:39:31
User entered '802 (802)'	System	08 Aug 2020 14:38:36

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:15:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 20:15:32
Data point term sent to Coder	System	06 Nov 2020 14:08:50
Coding entries removed.	Reagan Reed (b) (4)	06 Nov 2020 14:08:08
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:46:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 12:13:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 12:13:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN;DOXYLAMINE;PARA CETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 12:11:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 12:11:26
Data point term sent to Coder	System	09 Aug 2020 15:40:02
User entered 'Nyquil (acetaminophen/dextromethorphan/doxylamine)'	Heather Leary (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:01
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Reagan Reed (b) (4)	06 Nov 2020 14:08:08
	(b) (4)	
User entered 'Covid-19' reason for change: Data Entry Error	Reagan Reed (b) (4)	06 Nov 2020 14:08:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:03
User entered 'Fever/coughing'	Heather Leary (b) (4)	09 Aug 2020 15:39:20
	(b) (4)	

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:05
User entered '325/15/6.25'	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:10
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:40
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:43
User entered 'as needed (PRN)'	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:45
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:47
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:49
User entered empty.	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:53
User entered '7 Aug 2020'	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:47:58
User entered '0'	Heather Leary (b) (4) (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source, medication stop date is 10Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:08:22
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:08:20
Query 'Per source, medication stop date is 10Aug20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:50:39
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:50:31
User opened query 'Per source, medication stop date is 10Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:48:26
User entered 'Yes (Y)'	Heather Leary (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:08:23
User entered '10 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:50:31
User entered empty.	Heather Leary (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per source, the medication was not taken for a solicited event. Please verify and update accordingly.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:08:29
	(b) (4), (b) (6)	13 Oct 2020 20:08:27
Query 'Per source, the medication was not taken for a solicited event. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:50:47
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:50:31
User opened query 'Per source, the medication was not taken for a solicited event. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:49:05
User entered 'Yes (Y)'	Heather Leary (b) (4)	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Aug 2020 15:39:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:50:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:24:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:24:16
Data point term sent to Coder	System	11 Aug 2020 13:35:51
User entered 'Azithromycin'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:50:37
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:50:39
User entered 'COVID-19'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: It was noted that 2 tabs were given. Please review if 500 mg would be a more appropriate dose. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:50:57
Query 'Per DM CLR: It was noted that 2 tabs were given. Please review if 500 mg would be a more appropriate dose. Update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	06 Nov 2020 14:12:54
DataPoint Un-verified.	Reagan Reed (b) (4)	06 Nov 2020 14:10:14
User entered '500' reason for change: Data Entry Error	Reagan Reed (b) (4)	06 Nov 2020 14:10:14
User opened query 'Per DM CLR: It was noted that 2 tabs were given. Please review if 500 mg would be a more appropriate dose. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:33:51
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:50:40
User entered '250'	Heather Leary (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:50:44
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:50:46
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 14:51:13
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'updated' (Site from System).	Reagan Reed (b) (4)	06 Nov 2020 14:10:51
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	06 Nov 2020 14:10:14
DataPoint Un-verified.	Reagan Reed (b) (4)	06 Nov 2020 14:10:14
User entered 'once (ONCE)' reason for change: Data Entry Error	Reagan Reed (b) (4)	06 Nov 2020 14:10:14
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:50:48
User entered 'other (OTHER)'	Heather Leary (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

If frequency is Other, specify

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please record decrease in dose in a separate entry. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:51:14
Query 'Per DM CLR: Please record decrease in dose in a separate entry. Update as appropriate.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	06 Nov 2020 14:11:01
DataPoint Un-verified.	Reagan Reed (b) (4)	06 Nov 2020 14:10:14
User entered empty; reason for change Data Entry Error	Reagan Reed (b) (4)	06 Nov 2020 14:10:14
User opened query 'Per DM CLR: Please record decrease in dose in a separate entry. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:29:26
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:07
User entered '2 tabs first day, then 1 a day for the next 4 days'	Heather Leary (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:09
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:10
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:15
User entered '9 Aug 2020'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:22
User entered '0'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:20
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:04:35
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 15:04:46
User entered 'No (N)' reason for change: Data Entry Error	Afifah Ayub (b) (4) (b) (4)	21 Sep 2020 15:04:37
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:35:06
User entered 'Yes (Y)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:26
User entered '13 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	21 Sep 2020 15:04:37
User entered empty.	Heather Leary (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:29
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 13:35:20

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:46:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:46:18
Data point term sent to Coder	System	11 Aug 2020 13:36:52
User entered 'Zinc sulfate'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:52:14
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:13:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:13:22
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 11:34:35
User entered 'No (N)'	(b) (4), (b) (6) Heather Leary (b) (4) (b) (4)	01 Oct 2020 15:51:49 11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:51
User entered 'COVID19/health supplement'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:54
User entered '50'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:51:58
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:52:01
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:52:05
User entered 'once daily (QD)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:52:07
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:52:09
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:52:11
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:52:13
User entered '9 Aug 2020'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:52:15
User entered '0'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per source, medication was stopped on 14Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 20:06:53
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:06:51
Query 'Per source, medication was stopped on 14Aug20. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Afifah Ayub (b) (4)	01 Oct 2020 17:51:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 17:51:16
User opened query 'Per source, medication was stopped on 14Aug20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 15:52:57
User entered 'Yes (Y)'	Heather Leary (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 20:06:55
User entered '14 Aug 2020' reason for change: Data Entry Error	Afifah Ayub (b) (4)	01 Oct 2020 17:51:16
User entered empty.	Heather Leary (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:53:00
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 13:36:03

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

Name of Medication

Audit	User	Time (GMT)
User closed query 'Start of medication occurred one week after Subject received first dose. Please confirm if this was due to worsening of condition. If so, please add to AE log. ' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 17:25:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:47:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 18:47:24
Data point term sent to Coder	System	26 Oct 2020 15:30:15
Query 'Start of medication occurred one week after Subject received first dose. Please confirm if this was due to worsening of condition. If so, please add to AE log. ' answered with 'updated per source' (Site from CRA).	Reagan Reed (b) (4)	26 Oct 2020 15:29:38
Coding entries removed.	Reagan Reed (b) (4)	26 Oct 2020 15:29:32
User opened query 'Start of medication occurred one week after Subject received first dose. Please confirm if this was due to worsening of condition. If so, please add to AE log. ' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 04:05:08
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 13:38:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 13:38:06
Data point term sent to Coder	System	11 Aug 2020 13:36:53

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Amlodipine'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:13
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 16:44:56
DataPoint Un-verified.	Reagan Reed (b) (4)	26 Oct 2020 15:29:32
User entered 'Worsening Hypertension' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 15:29:32
DataPoint Verified.	Reagan Reed (b) (4)	26 Oct 2020 15:29:32
	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 15:55:16
User entered 'Hypertension'	Heather Leary (b) (4)	11 Aug 2020 13:36:39
	(b) (4)	

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:17
User entered '5'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:19
User entered 'mg (mg)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:20
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:22
User entered 'once daily (QD)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:25
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:27
User entered 'Oral (ORAL)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:31
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:34
User entered '10 Aug 2020'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:39
User entered '0'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:49:24
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'confirmed ongoing' (Site from DM).	Reagan Reed (b) (4)	06 Nov 2020 14:18:59
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:35:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:50
User entered 'Yes (Y)'	Heather Leary (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:55
User entered empty.	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 15:55:56
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 13:36:39

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 14:12:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 14:12:34
Data point term sent to Coder	System	06 Nov 2020 14:12:09
User entered 'Azithromycin'	Reagan Reed (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Indication](#)

Audit	User	Time (GMT)
User entered 'Covid-19'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Aug 2020'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Reagan Reed (b) (4) (b) (4)	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:47:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 14:12:06

US3212016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:47:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Heather Leary (b) (4) (b) (4)	05 Aug 2020 14:31:50

US3212016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:47:01

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020'	Afifah Ayub (b) (4) (b) (4)	17 Nov 2020 14:13:33

US3212016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:47:01

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Reagan Reed (b) (4)	23 Nov 2020 17:45:17
User closed query 'Per CDM: it appears event of COVID-19 and related Covid assessments were removed yet reason for discontinuation is recorded as AE of Cobid-19. Please reconcile and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:05:04
User entered 'Other (OTHER)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	18 Nov 2020 16:14:39
Query 'Per CDM: it appears event of COVID-19 and related Covid assessments were removed yet reason for discontinuation is recorded as AE of Cobid-19. Please reconcile and make all applicable updates.' answered with 'AE is in record #1.' (Site from DM).	Afifah Ayub (b) (4)	18 Nov 2020 16:12:49
User opened query 'Per CDM: it appears event of COVID-19 and related Covid assessments were removed yet reason for discontinuation is recorded as AE of Cobid-19. Please reconcile and make all applicable updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:38:23
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Afifah Ayub (b) (4)	17 Nov 2020 14:14:42
User entered 'Due to SARS-COV-2 (COVID)'	Afifah Ayub (b) (4)	17 Nov 2020 14:13:33

US3212016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:47:01

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: please record AE record number instead of details.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:24:48
Query 'Per CDM: please record AE record number instead of details.' answered with 'updated' (Site from DM).	Reagan Reed (b) (4)	23 Nov 2020 17:45:21
User entered empty; reason for change Data Entry Error	(b) (4)	23 Nov 2020 17:45:17
User opened query 'Per CDM: please record AE record number instead of details.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 22:25:53
User entered 'COVID 19 positive results' reason for change: Data Entry Error	Afifah Ayub (b) (4)	18 Nov 2020 16:14:39
User entered 'COVID 19' reason for change: Data Entry Error	Afifah Ayub (b) (4)	17 Nov 2020 14:14:55
User entered 'Positive COVID results' reason for change: Data Entry Error	Afifah Ayub (b) (4)	17 Nov 2020 14:14:42
User entered empty.	Afifah Ayub (b) (4)	17 Nov 2020 14:13:33

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'USA-US115-2020-MRNA-1273-P301000001'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:57

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:57

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:28:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 18:49:25
User entered 'US' (non-conformant).	System	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 18:49:44
User entered '1'	System	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'USA-US115-2020-MRNA-1273-P301000001'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:57

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:57

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:28:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 18:49:25
User entered 'US' (non-conformant).	System	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 18:49:44
User entered '1'	System	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:47:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
User entered '18/Aug/2020 13:25'	System	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:47:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 18:49:25
User entered 'I'	(b) (4), (b) (6)	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'USA-US115-2020-MRNA-1273-P301000001'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 17:25:38
User entered 'No (N)'	System	18 Aug 2020 17:23:41

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: User entered 'Vicki'	System	14 Sep 2020 21:42:57

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: User entered 'Miller'	System	14 Sep 2020 21:42:57

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:28:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Aug 2020 18:49:25
User entered 'US' (non-conformant).	System	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:47:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Aug 2020 18:49:44
User entered '1'	System	18 Aug 2020 17:25:56

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:47:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
User entered '25/Aug/2020 14:49'	System	25 Aug 2020 18:49:44

US3212016

Folder: SAE USA-US115-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:47:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:43
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 18:49:44