

US3322006 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:57:50

All time stamps listed in this document are displayed in GMT

**US3322006**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:57:50**

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[Participant ID](#)

US3322006

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

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US3322006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:57:50

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:50

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:50

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:50

Condition	RECURRENT BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:50

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN DEC 2017
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 DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:57:50

Condition	INTERMITTENT TENSION HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:57:50

Condition	NUMBNESS/TINGLING OF HANDS/FEET
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:57:50

Condition	VICODIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:57:50

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:57:50

Condition	UTERINE MYOMAS
Start date (dd MMM yyyy)	UN JUL 2017
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 DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:57:50

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:11 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 16:11
Height ( <i>xxx.x</i> )	67 in
Weight ( <i>xxx.x</i> )	256.6 lb
BMI ( <i>xxx.x</i> )	40.27327 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	75 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input checked="" type="radio"/>
	Post-menopausal <input type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> )	UN DEC 2017
Date of surgery unknown	False
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> ) _____	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

PT IS A 50 YEAR OLD AFRICAN  
AMERICAN FEMALE WITH A  
BMI >40. PT AND HUSBAND ARE  
(b) (6) DELIVERY  
DRIVERS, WHO ARE IN  
CONTACT WITH APPROX 10  
PEOPLE IN THE WAREHOUSE  
WHILE PICKING UP THE  
(b) (6)

**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) False

**Resides in high density housing** (e.g., high rise apartments with  
shared entrances or elevators) False

**Resides in low density, multi-family setting without** (e.g.,  
apartments complex without shared entrances or elevators, duplexes) False

**Resides in a single family home** (i.e., detached housing) True

**Other** True

**Specify**

PT GOES TO THE STORES AT  
LEAST ONCE A WEEK AND  
LIVES IN A HOUSE WITH 3  
OTHER PEOPLE. HER  
DAUGHTER LIVES WITH HER  
AND WORKS IN AN OFFICE  
FULL-TIME.

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 144024

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:50

Height	67 in
Weight	259.4 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

Height	67 in
Weight	259.4 lb
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	09:47 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:47
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

Height	67 in
Weight	259.4 lb
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)	17 AUG 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:44
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 12:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	17 AUG 2020
Collection time ( <i>00:00-23:59</i> )	11:08 (24 HR)
Collection date and time (derived)	17 AUG 2020 11:08

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:50

Collection date ( <i>dd MMM yyyy</i> )			17 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	17 AUG 2020 11:05
Nasopharyngeal Swab 2	No		

US3322006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

**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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 12:46

PC Open Date & Time

17 AUG 2020 12:26

PC Close Date & Time

17 AUG 2020 14:56

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

**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 98.2 °F

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

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

PC Time Stamp	17 AUG 2020 19:21
PC Open Date & Time	17 AUG 2020 15:51
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:50

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 19:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:50

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**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.

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

---

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

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PC Time Stamp

19 AUG 2020 19:06

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PC Open Date & Time

19 AUG 2020 12:00

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PC Close Date & Time

20 AUG 2020 11:59

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US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:50

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**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

97.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

20 AUG 2020 19:29

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PC Open Date & Time

20 AUG 2020 12:00

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PC Close Date & Time

21 AUG 2020 11:59

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US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:50

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.8 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

21 AUG 2020 20:06

---

PC Open Date & Time

21 AUG 2020 12:00

---

PC Close Date & Time

22 AUG 2020 11:59

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US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:50

**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

97.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 AUG 2020 20:29

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:50

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.7 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

23 AUG 2020 19:32

---

PC Open Date & Time

23 AUG 2020 12:00

---

PC Close Date & Time

24 AUG 2020 11:59

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US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

**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

17 AUG 2020 12:48

PC Open Date & Time

17 AUG 2020 12:26

PC Close Date & Time

17 AUG 2020 14:56

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 19:22

PC Open Date & Time

17 AUG 2020 15:51

PC Close Date & Time

18 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:50

**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

18 AUG 2020 19:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:50

**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

19 AUG 2020 19:07

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:50

**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

20 AUG 2020 19:26

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:50

**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

21 AUG 2020 20:06

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:50

**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

22 AUG 2020 20:30

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:50

**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

23 AUG 2020 19:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

**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 ☐

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 12:49
PC Open Date & Time	17 AUG 2020 12:26
PC Close Date & Time	17 AUG 2020 14:56

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

**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 ☐

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 19:22
PC Open Date & Time	17 AUG 2020 15:51
PC Close Date & Time	18 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:50

**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 ☒

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:50

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 19:16
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:50

**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 ☒

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:50

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 19:07
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59



US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:50

**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 ☒

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:50

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:26
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:50

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 ☒

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:50

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 20:07
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:50

**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 ☒

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:50

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:30
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:50

**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 ☒

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:50

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:33
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59



US3322006

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 26 Nov 2020 10:57:50

**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

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 9

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

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 8

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

None ☐

**ACHES IN SEVERAL JOINTS**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 9

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

None ☐

**ACHES IN SEVERAL JOINTS**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 26 Nov 2020 10:57:50

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:57:50

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

Was Contact Attempted?

Yes ☒

No ☐

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

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

Was Contact Attempted?

Yes ☒

No ☐

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

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

Was Contact Attempted?

Yes ☒

No ☐

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

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3322006**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:50**

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 \_\_\_\_\_

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

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

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
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	

US3322006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

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.*



US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

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? \_\_\_\_\_

US3322006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:50

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:50

Collection date ( <i>dd MMM yyyy</i> )			
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

**US3322006**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:57:50**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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21 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

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25 OCT 2020 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 NOV 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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04 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2020 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2020 23:59



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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02 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2020 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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09 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2020 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2020 23:59



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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30 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 166

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

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

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

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

10 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

17 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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03 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 208

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

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

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

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 MAR 2021 00:01

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14 MAR 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

17 MAR 2021 00:01

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21 MAR 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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24 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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31 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

07 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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14 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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28 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 MAY 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 MAY 2021 23:59
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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAY 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 <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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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<a href="#">Patient Cloud Open Date &amp; Time</a>	18 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2021 23:59
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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59
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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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20 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 OCT 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 <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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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15 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 DEC 2021 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 MAR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUN 2022 23:59



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 <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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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15 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUN 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUL 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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



US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 AUG 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 AUG 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 <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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**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 ☐

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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 <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"/>

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:50

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

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

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

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19 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:50

Date of Contact	14 SEP 2020
Time of Contact	00:00
Date and Time of Contact (derived)	14 SEP 2020 00:00
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"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

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"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 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)	298 of 2151	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

	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"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

	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"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 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)	302 of 2151	

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Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

	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"/>



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Form: Symptom Log (2)

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	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"/>

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.5 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 checked="" type="radio"/>
v6.020 DTW (1102)	306 of 2151	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

	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 type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

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

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 checked="" type="radio"/>
v6.020 DTW (1102)	310 of 2151	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>



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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

	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 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"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 checked="" type="radio"/>
v6.020 DTW (1102)	314 of 2151	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

	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 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"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	318 of 2151	

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

	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"/>



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Form: Symptom Log (6)

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	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 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)	322 of 2151	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

	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	21 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

	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"/>



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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

	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	22 SEP 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 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)	330 of 2151	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[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"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

	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	23 SEP 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.1 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)	334 of 2151	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

	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"/>



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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[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"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

	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	24 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.1 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)	338 of 2151	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

	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 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"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

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"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

	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	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.7 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"/>
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Form: Symptom Log (12)

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	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 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"/>



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Form: Symptom Log (12)

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	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"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

Symptom Day

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

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.1 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"/>
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Form: Symptom Log (13)

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	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 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"/>

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Form: Symptom Log (13)

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	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"/>

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Form: Symptom Log (14)

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Symptom Day

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

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (14)

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	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 type="checkbox"/>
	Mild	<input checked="" 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"/>



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Form: Symptom Log (14)

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	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"/>

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Form: Symptom Log (15)

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Symptom Day

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

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.3 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)	354 of 2151	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

	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 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"/>

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Form: Symptom Log (15)

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	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"/>

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Form: Symptom Log (16)

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[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"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 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)	358 of 2151	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

	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"/>



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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 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)	362 of 2151	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 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)	366 of 2151	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

	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"/>



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Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[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"/>

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Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 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)	370 of 2151	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

	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 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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)	374 of 2151	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

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



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Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

	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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:57:50

Date of Visit	14 SEP 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	14 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input checked="" type="radio"/>
Other, specify	NASOPHARYNGEAL SWAB AND BLOOD
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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

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

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

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

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 17 SEP 2020

End Date 17 SEP 2020

Oxygen Saturation 91 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

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:

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

**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 \_\_\_\_\_

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:57:50

[Generate Next COVID-19 Assessment](#)

Yes ☐  
No ☒

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:57:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 SEP 2020
Day 5	Yes	18 SEP 2020
Day 7	Yes	21 SEP 2020
Day 9	Yes	23 SEP 2020
Day 14	Yes	28 SEP 2020
Day 21	Yes	5 OCT 2020
Day 28	Yes	8 OCT 2020

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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	SICKD1



US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:15 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:15
Height ( <i>xxx.x</i> )	67 in
Weight ( <i>xxx.x</i> )	256.6 lb
Temperature ( <i>xxx.x</i> )	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	91 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3322006

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:57:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 SEP 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SICKD28

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:30 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 13:30
Height ( <i>xxx.x</i> )	67 in
Weight ( <i>xxx.x</i> )	255 lb
Temperature ( <i>xxx.x</i> )	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	69 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	104 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3322006

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:57:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 OCT 2020

US3322006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:50

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

AEID	USA-US060-2020-MRNA-1273-P30 1000003
Adverse event	SYMPTOMATIC COVID -19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 OCT 2020
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	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

AEID	
Adverse event	HEMATOCHEZIA
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)	28 SEP 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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

AEID	
Adverse event	ELEVATED BLOOD PRESSURE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	08 OCT 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 type="radio"/> Grade 3/Severe <input checked="" 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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:57:50

---

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

Yes ☒

No ☐

---

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

---

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

Name of Medication	ALBUTEROL SULFATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ASTHMA
Dose per administration	90
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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

	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 ( <i>dd MMM yyyy</i> )	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> ) <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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

Name of Medication ASPIRIN (NSAID\*)  
845MG/CAFFEINE 65 MG(BC  
POWDER)

Prophylaxis Yes ☐  
No ☒

Indication INTERMITTENT TENSION  
HEADACHES

Dose per administration 845/65

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:50

Name of Medication ASPIRIN (NSAID\*)  
845MG/CAFFEINE 65 MG(BC  
POWDER)

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 845/65

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 ☐

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:50

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

Name of Medication ASPIRIN (NSAID\*) 845  
MG/CAFFEINE 65 MG(BC  
POWDER)

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 845/65

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 ☐

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

	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)	22 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)	23 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

Name of Medication	LORATADINE (CLARITIN)
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SEASONAL ALLERGIES
Dose per administration	10
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"/>



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

Name of Medication	ANTIHISTAMINE EYE DROPS [UNKNOWN]
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	2
Dose unit	mg <input 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 checked="" type="radio"/>
If dose unit is Other, specify	DROPS
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 checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:57:50

Name of Medication NYQUIL [ACETAMINOPHEN,  
DEXTROMETHORPHAN  
HYDROBROMIDE,  
DOXYLAMINE SUCCINATE  
PHENYLEPHRINE  
HYDROCHLORIDE]

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 650/20/12.5/10

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 ☐

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:57:50

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 SEP 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)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
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"/>

US3322006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:57:50

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:50

Date of dosing discontinuation (dd MMM yyyy)

9 SEP 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 \_\_\_\_\_

US3322006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:57:50

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 ☐



US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

SAEID	USA-US060-2020-MRNA-1273-P301000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:57:50

SAEID	USA-US060-2020-MRNA-1273-P301000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/SEP/2020 14:20
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

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:57:50

SAEID	USA-US060-2020-MRNA-1273-P301000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/SEP/2020 12:43
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

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:57:50

SAEID	USA-US060-2020-MRNA-1273-P301000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/OCT/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

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:57:50

SAEID	USA-US060-2020-MRNA-1273-P301000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	
<b>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.</b>	

Audit

US3322006 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

**US3322006**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:57:50**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3322006'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	14 Aug 2020 22:34:15

US3322006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:28



US3322006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 22:34:16

US3322006

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:28

**US3322006**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	14 Aug 2020 22:41:28

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 22:34:17

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[Age](#)

Audit	User	Time (GMT)
User entered '50'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

**US3322006**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:57:50**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	14 Aug 2020 22:41:49

**US3322006**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:57:50**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '50'	System	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49



US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

White

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[Black](#)

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49



US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

Unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:50

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:04

**US3322006**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	14 Aug 2020 22:42:04

**US3322006**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2020'	System	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:04



US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	14 Aug 2020 22:34:16

US3322006

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:57:50

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:42:22

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:50

Condition

Audit	User	Time (GMT)
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)	15 Aug 2020 00:22:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:41
Data point term sent to Coder	System	14 Aug 2020 22:44:04
User entered 'Seasonal Allergies'	Frances Saubon (b) (4)	14 Aug 2020 22:43:08
	(b) (4)	

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN UNK 1972'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:08



**US3322006**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:08

**US3322006**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:57:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:08

**US3322006**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1972'	System	14 Aug 2020 22:43:08

**US3322006**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '1972'	System	14 Aug 2020 22:43:08

**US3322006**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:43:08

**US3322006**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:43:08



US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:50

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:28:52
Query 'Per DM CLR: Please note that there is no Con Frances Saubon Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Concomitant medication page is updated' (Site from DM).	(b) (4)	22 Sep 2020 20:25:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:43:59
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)	15 Aug 2020 00:22:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:16
Data point term sent to Coder	System	14 Aug 2020 22:44:04
User entered 'Asthma'	Frances Saubon (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:50

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:36

**US3322006**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	14 Aug 2020 22:43:36

**US3322006**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2012'	System	14 Aug 2020 22:43:36



**US3322006**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:43:36

**US3322006**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:16
Data point term sent to Coder	System	14 Aug 2020 22:44:06
User entered 'Recurrent Back Pain'	Frances Saubon (b) (4)	14 Aug 2020 22:43:51
	(b) (4)	

**US3322006**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:51

**US3322006**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:51

**US3322006**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:51



**US3322006**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	14 Aug 2020 22:43:51

**US3322006**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2015'	System	14 Aug 2020 22:43:51

**US3322006**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:43:51

**US3322006**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:50

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that a surgical procedure of hysterectomy was performed = UN DEC 2017. However, the reason provided in the childbearing potential ecrf is OTHER and the date of surgical sterilization was not indicated. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:29:52
Query 'Per DM CLR: Please note that a surgical procedure of hysterectomy was performed = UN DEC 2017. However, the reason provided in the childbearing potential ecrf is OTHER and the date of surgical sterilization was not indicated. Please review and update if appropriate. Otherwise, clarify. ' answered with 'Data updated' (Site from DM).	Frances Saubon (b) (4)	22 Sep 2020 20:16:56
User opened query 'Per DM CLR: Please note that a surgical procedure of hysterectomy was performed = UN DEC 2017. However, the reason provided in the childbearing potential ecrf is OTHER and the date of surgical sterilization was not indicated. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:44:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:16
Data point term sent to Coder	System	14 Aug 2020 22:45:06
User entered 'Hysterectomy'	Frances Saubon (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN Dec 2017'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:50

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:26

**US3322006**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:26



US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN Dec 2017'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:57:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:26

**US3322006**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	14 Aug 2020 22:44:26

**US3322006**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 22:44:26

**US3322006**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	14 Aug 2020 22:44:26

**US3322006**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:57:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headaches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 07:27:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 07:27:07
Data point term sent to Coder	System	14 Aug 2020 22:45:06
User entered 'Intermittent Tension Headaches'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN UNK 1980'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:50



US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:57:50

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:50

**US3322006**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:50

**US3322006**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:57:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:50

**US3322006**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	14 Aug 2020 22:44:50

**US3322006**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '1980'	System	14 Aug 2020 22:44:50

**US3322006**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:44:50

**US3322006**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:44:50



US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:57:50

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Tingling feet/hands - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:43:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:43:12
Data point term sent to Coder	System	14 Aug 2020 22:46:07
User entered 'Numbness/Tingling of Hands/Feet'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:57:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:10

**US3322006**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:57:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:10

**US3322006**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	14 Aug 2020 22:45:10

**US3322006**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2015'	System	14 Aug 2020 22:45:10



**US3322006**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:45:10

**US3322006**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:57:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:19
Data point term sent to Coder	System	14 Aug 2020 22:46:07
User entered 'Vicodin Allergy'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:33

**US3322006**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:33

**US3322006**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:57:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:33



**US3322006**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	14 Aug 2020 22:45:33

**US3322006**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2015'	System	14 Aug 2020 22:45:33

**US3322006**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:45:33

**US3322006**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:57:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:20
Data point term sent to Coder	System	14 Aug 2020 22:46:07
User entered 'Migraine Headaches'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN UNK 1986'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:57:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:50



US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:57:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:45:50

**US3322006**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 1986'	System	14 Aug 2020 22:45:50

**US3322006**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '1986'	System	14 Aug 2020 22:45:50

**US3322006**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:45:50

**US3322006**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:57:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine myoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 05:59:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 05:59:39
Data point term sent to Coder	System	14 Aug 2020 22:47:08
User entered 'Uterine Myomas'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN Jul 2017'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:46:12



US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:57:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:46:12

**US3322006**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'UN Dec 2017' reason for change: Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 22:04:47
User entered 'UN Jul 2017'	Frances Saubon (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:57:50

Stop date completely unknown

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, Stop date of MH = UN July 2017. However, Hysterectomy's start/stop date recorded is UN DEC 2017 which is unexpected. Review and reconcile dates as appropriate. Else, clarify. '(Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:30:45
Query 'Per DM CLR: Please note, Stop date of MH = Frances Saubon UN July 2017. However, Hysterectomy's start/stop date recorded is UN DEC 2017 which is unexpected. Review and reconcile dates as appropriate. Else, clarify. ' answered with 'Data updated per query resolution. Thank you' (Site from DM).	(b) (4)	22 Sep 2020 22:05:14
User opened query 'Per DM CLR: Please note, Stop date of MH = UN July 2017. However, Hysterectomy's start/stop date recorded is UN DEC 2017 which is unexpected. Review and reconcile dates as appropriate. Else, clarify. '(Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:45:57
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:46:12

**US3322006**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jul 2017'	System	14 Aug 2020 22:46:12

**US3322006**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 22:46:12

**US3322006**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Dec 2017'	System	22 Sep 2020 22:04:47
User entered 'Jul 2017'	System	14 Aug 2020 22:46:12

**US3322006**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2017'	System	14 Aug 2020 22:46:12



US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:57:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:36:48
Data point term sent to Coder	System	16 Nov 2020 20:36:20
User entered 'Hemorrhoids'	Frances Saubon (b) (4)	16 Nov 2020 20:35:45
	(b) (4)	

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:57:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:57:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:57:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 20:35:45

**US3322006**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	16 Nov 2020 20:35:45

**US3322006**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '2010'	System	16 Nov 2020 20:35:45



**US3322006**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:35:45

**US3322006**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '16:11'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

**US3322006**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '14 Aug 2020 16:11'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '67' in	Frances Saubon (b) (4)	14 Aug 2020 22:47:36
DataPoint set to visible.	(b) (4) System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '256.6' lb	Frances Saubon (b) (4)	14 Aug 2020 22:47:36
DataPoint set to visible.	(b) (4) System	14 Aug 2020 22:42:08



**US3322006**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Amendment Manager: User entered '40.27327'	System	16 Sep 2020 23:58:15
User entered '40.3'	System	14 Aug 2020 22:47:36
DataPoint set to visible.	System	14 Aug 2020 22:42:08

**US3322006**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	14 Aug 2020 22:47:36
DataPoint set to visible.	System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.9' F	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

**US3322006**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '18'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36



US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:43

US3322006

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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 12:58:15
Comment added 'Screening visit was conducted 14-Aug-2020 and Physical exam was also conducted 14-Aug-2020'.	Elisa Moralez (b) (4)	18 Aug 2020 14:59:48
Comment added 'visit date and physical examination date are identical'.	(b) (4)	17 Aug 2020 20:53:23
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	Elisa Moralez (b) (4)	17 Aug 2020 19:13:50
User entered '14 Aug 2020'	Frances Saubon (b) (4)	14 Aug 2020 22:47:43

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Aug 2020'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:48:37



US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

If No, what is the reason?

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 20:16:10
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	(b) (4)	14 Aug 2020 22:50:44
User entered 'Other (OTHER)' reason for change: Data Entry Error	Frances Saubon (b) (4)	14 Aug 2020 22:50:44
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Aug 2020 22:48:37
User entered empty.	Frances Saubon (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 20:16:10
User entered 'Hysterectomized'	Frances Saubon (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'UN Dec 2017' reason for change: Data	Frances Saubon (b) (4)	22 Sep 2020 20:16:10
Entry Error	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	14 Aug 2020 22:48:37
	(b) (4)	

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:57:50

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27



US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27



US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

[Specify](#)

Audit	User	Time (GMT)
User entered 'Pt is a 50 year old African American female with a BMI >40. PT and husband are (b) (6) delivery drivers, who are in contact with approx 10 people in the warehouse while picking up the (b) (6)	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27



US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '1'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:50

[Specify](#)

Audit	User	Time (GMT)
User entered 'Pt goes to the stores at least once a week and lives in a house with 3 other people. Her daughter lives with her and works in an office full-time.'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported underUnscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:43:04
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported underUnscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' ' answered with 'Sample is collected on 08-Oct-2020 for Illness Visit Day 28. A DCF has been submitted to reflect changes.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 14:52:07
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported underUnscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:11:07
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:13:50

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:13:50

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:13:50

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	17 Aug 2020 19:13:50



US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	17 Aug 2020 15:59:51

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

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 04:44:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:44:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 15:59:51
User entered '144024' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Aug 2020 15:59:51

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Aug 2020 15:59:51

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:14:13



US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4)	22 Sep 2020 22:04:13
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:21:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:26:22

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:50

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:50:41
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'Per source, Screening visit and V1 visit were on 14-Aug-2020 and 17-Aug-2020, respectively.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:00:48
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:21:07
User entered '67' in reason for change: Data Entry Error	Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:50

Weight

Audit	User	Time (GMT)
User entered '259.4' lb reason for change: Data Entry Error	Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:50

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:50:41
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'Per source, Screening visit and V1 visit were on 14-Aug-2020 and 17-Aug-2020, respectively.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:00:48
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:21:07
User entered '67' in reason for change: Data Entry Error	Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:50

Weight

Audit	User	Time (GMT)
User entered '259.4' lb reason for change: Data Entry Error	Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:24:19
User entered '17 Aug 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:18:56
User entered '14 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56



US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '09:47' reason for change: Data Entry Error	Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User entered '16:11'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 09:47'	System	17 Aug 2020 19:24:19
User entered '14 Aug 2020 16:11'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '96.9' F	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70' reason for change: Data Entry Error	Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User entered '75'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:57:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User entered '18'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56



US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80' reason for change: Data Entry Error	Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User entered '84'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:50

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 16:50:41
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'Per source, Screening visit and V1 visit were on 14-Aug-2020 and 17-Aug-2020, respectively.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:00:48
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:21:07
User entered '67' in reason for change: Data Entry Error	Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:50

[Weight](#)

Audit	User	Time (GMT)
User entered '259.4' lb reason for change: Data Entry	Frances Saubon (b) (4)	18 Aug 2020 15:49:33
Error	(b) (4)	
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56
	(b) (4)	

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56



US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
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)	18 Aug 2020 17:50:16
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 source' (Site from System).	Frances Saubon (b) (4)	17 Aug 2020 19:46:00
User opened 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).		17 Aug 2020 19:18:56
User entered '12:44'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:44'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 05:58:05
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Frances Saubon (b) (4)	17 Sep 2020 13:18:28
answered with 'NCS' (Site from System).	(b) (4)	
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:58:15
User entered '96.5' F	Frances Saubon (b) (4)	17 Aug 2020 19:18:56
	(b) (4)	

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

Pulse (xxx)

Audit	User	Time (GMT)
User entered '66'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56



**US3322006**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '18'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '147'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:25:33



US3322006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:25:33

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:06'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 17:08:45

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:57:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:06'	System	17 Aug 2020 17:08:45



US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:25:58

US3322006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:25:58

US3322006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:08'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:25:58

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:57:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:08'	System	17 Aug 2020 19:25:58

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26



US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:05'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:57:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:05'	System	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:50

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 19:26:26



US3322006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:31

**US3322006**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:57:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 19:26:31

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered 'Yes (Y)'	System	17 Aug 2020 17:46:55

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered '96.5'	System	17 Aug 2020 17:46:55

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered 'No (N)'	System	17 Aug 2020 17:46:55

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:52', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered '17 Aug 2020 12:46'	System	17 Aug 2020 17:46:55

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:26'	System	17 Aug 2020 17:08:45



US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 14:56'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01'	System	18 Aug 2020 00:21:53
User entered 'Yes (Y)'	System	18 Aug 2020 00:21:53

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:44', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01'	System	18 Aug 2020 00:21:53
User entered '98.2'	System	18 Aug 2020 00:21:53

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01'	System	18 Aug 2020 00:21:53
User entered 'No (N)'	System	18 Aug 2020 00:21:53

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:51', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01'	System	18 Aug 2020 00:21:53
User entered '17 Aug 2020 19:21'	System	18 Aug 2020 00:21:53

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 15:51'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:08:45



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 2'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:14:55', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered 'Yes (Y)'	System	19 Aug 2020 00:15:21

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:08', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered '98.1'	System	19 Aug 2020 00:15:21

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered 'No (N)'	System	19 Aug 2020 00:15:21

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:17', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered '18 Aug 2020 19:15'	System	19 Aug 2020 00:15:21

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 3'	System	17 Aug 2020 17:08:45



US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:34', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered 'Yes (Y)'	System	20 Aug 2020 00:06:47

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered '97.3'	System	20 Aug 2020 00:06:47

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:41', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered 'No (N)'	System	20 Aug 2020 00:06:47

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:44', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered '19 Aug 2020 19:06'	System	20 Aug 2020 00:06:47

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:57:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 4'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered 'Yes (Y)'	System	21 Aug 2020 00:29:40



US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:34', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered '97.3'	System	21 Aug 2020 00:29:40

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:37', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered 'No (N)'	System	21 Aug 2020 00:29:40

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered '20 Aug 2020 19:29'	System	21 Aug 2020 00:29:40

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:57:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 5'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:03', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered 'Yes (Y)'	System	22 Aug 2020 01:06:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:09', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered '97.8'	System	22 Aug 2020 01:06:23



US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered 'No (N)'	System	22 Aug 2020 01:06:23

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered '21 Aug 2020 20:06'	System	22 Aug 2020 01:06:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 6'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:37', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered 'Yes (Y)'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:41', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered '97.6'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered 'Yes (Y)'	System	23 Aug 2020 01:29:58



US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:50

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 'follow-up call revealed patient took asprin for headache' (Site from System).	(b) (4), (b) (6) (b) (4)	25 Aug 2020 12:52:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:50', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	Elisa Moralez (b) (4) (b) (4)	24 Aug 2020 17:34:51
User entered '1'	System	23 Aug 2020 01:29:58
	System	23 Aug 2020 01:29:58
	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:50', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered '0'	System	23 Aug 2020 01:29:58

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:53', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered '22 Aug 2020 20:29'	System	23 Aug 2020 01:29:58

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:57:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 7'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:10', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61addbc8466'	System	24 Aug 2020 00:32:23
User entered 'Yes (Y)'	System	24 Aug 2020 00:32:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61addbc8466'	System	24 Aug 2020 00:32:23
User entered '97.7'	System	24 Aug 2020 00:32:23



US3322006

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:17', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61addbc8466'	System	24 Aug 2020 00:32:23
User entered 'No (N)'	System	24 Aug 2020 00:32:23

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:19', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61addbc8466'	System	24 Aug 2020 00:32:23
User entered '23 Aug 2020 19:32'	System	24 Aug 2020 00:32:23

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-17T12:47:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 17:48:24

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:47:44', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'No (N)'	System	17 Aug 2020 17:48:24

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:12', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'No (N)'	System	17 Aug 2020 17:48:24



US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-17T12:48:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'None (1)'	System	17 Aug 2020 17:48:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:22', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered '17 Aug 2020 12:48'	System	17 Aug 2020 17:48:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:26'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 14:56'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-17T19:22:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'None (1)'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:02', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'No (N)'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:04', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'No (N)'	System	18 Aug 2020 00:22:18



US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-17T19:22:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'None (1)'	System	18 Aug 2020 00:22:18

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered '17 Aug 2020 19:22'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 15:51'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 2'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-18T19:15:22', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'None (1)'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'No (N)'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'No (N)'	System	19 Aug 2020 00:16:03



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-18T19:15:56', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'None (1)'	System	19 Aug 2020 00:16:03

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered '18 Aug 2020 19:15'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 3'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-19T19:07:09', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'None (1)'	System	20 Aug 2020 00:07:35

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'No (N)'	System	20 Aug 2020 00:07:35

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:15', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'No (N)'	System	20 Aug 2020 00:07:35



US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-19T19:07:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'None (1)'	System	20 Aug 2020 00:07:35

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered '19 Aug 2020 19:07'	System	20 Aug 2020 00:07:35

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 4'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-20T19:26:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'None (1)'	System	21 Aug 2020 00:26:37

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:24', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'No (N)'	System	21 Aug 2020 00:26:37

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:26', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'No (N)'	System	21 Aug 2020 00:26:37



US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-20T19:26:29', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'None (1)'	System	21 Aug 2020 00:26:37

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered '20 Aug 2020 19:26'	System	21 Aug 2020 00:26:37

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 5'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-21T20:06:27', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'None (1)'	System	22 Aug 2020 01:06:44

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'No (N)'	System	22 Aug 2020 01:06:44

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'No (N)'	System	22 Aug 2020 01:06:44



US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-21T20:06:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'None (1)'	System	22 Aug 2020 01:06:44

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:41', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered '21 Aug 2020 20:06'	System	22 Aug 2020 01:06:44

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 6'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-22T20:29:57', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'None (1)'	System	23 Aug 2020 01:30:09

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'No (N)'	System	23 Aug 2020 01:30:09

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:01', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'No (N)'	System	23 Aug 2020 01:30:09



US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-22T20:30:03', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'None (1)'	System	23 Aug 2020 01:30:09

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:06', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered '22 Aug 2020 20:30'	System	23 Aug 2020 01:30:09

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 7'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[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 (8a0987a97a70596a)', Time: '2020-08-23T19:32:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'None (1)'	System	24 Aug 2020 00:33:01

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:33', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'No (N)'	System	24 Aug 2020 00:33:01

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'No (N)'	System	24 Aug 2020 00:33:01



US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-23T19:32:56', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'None (1)'	System	24 Aug 2020 00:33:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:58', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered '23 Aug 2020 19:32'	System	24 Aug 2020 00:33:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:49:05

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:42', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:49', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:53', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-17T12:48:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'No (N)'	System	17 Aug 2020 17:49:05

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:49:02', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered '17 Aug 2020 12:49'	System	17 Aug 2020 17:49:05

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:26'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 14:56'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:08:45



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:20', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:23', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:26', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:28', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-17T19:22:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'No (N)'	System	18 Aug 2020 00:22:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:43', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered '17 Aug 2020 19:22'	System	18 Aug 2020 00:22:45



US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 15:51'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 2'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:08', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'No interference with activity (1)'	System	19 Aug 2020 00:16:26

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:13', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:16', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-18T19:16:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'No (N)'	System	19 Aug 2020 00:16:26

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:23', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered '18 Aug 2020 19:16'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 3'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'No interference with activity (1)'	System	20 Aug 2020 00:08:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:45', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:48', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:50', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:52', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-19T19:07:55', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'No (N)'	System	20 Aug 2020 00:08:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered '19 Aug 2020 19:07'	System	20 Aug 2020 00:08:01

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:57:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:08:45



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 4'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:25:52', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'No interference with activity (1)'	System	21 Aug 2020 00:26:18

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:25:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'Some interference with activity (2)'	System	21 Aug 2020 00:26:18

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:04', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'Some interference with activity (2)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:07', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'None (0)'	System	21 Aug 2020 00:26:18

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:09', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'None (0)'	System	21 Aug 2020 00:26:18

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:10', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'None (0)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-20T19:26:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'No (N)'	System	21 Aug 2020 00:26:18



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:16', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered '20 Aug 2020 19:26'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 5'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'No interference with activity (1)'	System	22 Aug 2020 01:07:49

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:20', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity (2)'	System	22 Aug 2020 01:07:49

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity (2)'	System	22 Aug 2020 01:07:49

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity (2)'	System	22 Aug 2020 01:07:49



US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Aug 2020 01:07:49

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:42', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'None (0)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-21T20:07:45', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'No (N)'	System	22 Aug 2020 01:07:49

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered '21 Aug 2020 20:07'	System	22 Aug 2020 01:07:49

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 6'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'No interference with activity (1)'	System	23 Aug 2020 01:30:54



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'No interference with activity (1)'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'None (0)'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:26', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'Some interference with activity (2)'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:37', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'None (0)'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'None (0)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-22T20:30:49', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'No (N)'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:51', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered '22 Aug 2020 20:30'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:08:45



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 7'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:03', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'No interference with activity (1)'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:07', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:10', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:13', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'No interference with activity (1)'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:15', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:17', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24



US3322006

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:57:50

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 (8a0987a97a70596a)', Time: '2020-08-23T19:33:19', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'No (N)'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered '23 Aug 2020 19:33'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 01:30:54
User entered 'Day 8'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 00:33:24
User entered 'Day 9'	System	24 Aug 2020 00:33:24



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 01:30:54
User entered 'Day 8'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:30:54

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 00:33:24
User entered 'Day 9'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 26 Nov 2020 10:57:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:33:24



**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 01:29:58
User entered 'Day 8'	System	23 Aug 2020 01:29:58

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:29:58

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:29:58

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 00:33:24
User entered 'Day 9'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:33:24

**US3322006**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:57:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:33:24

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:30

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:30



US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:30

**US3322006**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:57:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:30

US3322006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:34

**US3322006**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:57:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 13:16:34

US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:46

**US3322006**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:46

US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:46

**US3322006**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:57:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:46



US3322006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Sep 2020 13:16:50

**US3322006**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:57:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 13:16:50

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 14:22:01

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 16:09:01
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Elisa Moralez (b) (4)	14 Sep 2020 14:22:28
answered with 'attempts made 9/10 and 9/11 unsuccessful ' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 14:22:01
User entered '12 Sep 2020'	Elisa Moralez (b) (4)	14 Sep 2020 14:22:01
	(b) (4)	

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 14:22:01

**US3322006**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:57:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 14:22:01

US3322006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 14:22:33

**US3322006**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:57:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 14:22:33



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 08:10:57



**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 08:10:57

**US3322006**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:57:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:50

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered '14 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:16:30
User opened query 'Data is required. Please complete.' (Site from System).	Elisa Moralez (b) (4)	16 Sep 2020 19:03:14
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '9 Sep 2020'	System	16 Sep 2020 19:02:56
	Elisa Moralez (b) (4)	16 Sep 2020 19:02:56
	(b) (4)	
	Elisa Moralez (b) (4)	15 Sep 2020 19:57:29
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:50

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered '00:00' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:22:42
User opened query 'Data is required. Please complete.' (Site from System).	Elisa Moralez (b) (4)	16 Sep 2020 19:03:16
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '00:00'	System	16 Sep 2020 19:02:56
	Elisa Moralez (b) (4)	16 Sep 2020 19:02:56
	(b) (4)	
	Elisa Moralez (b) (4)	15 Sep 2020 19:57:29
	(b) (4)	



**US3322006**

**Folder: Covid-19 Assessment 14 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:57:50**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 00:00'	System	21 Sep 2020 20:01:35
User entered empty.	System	16 Sep 2020 19:02:56
User entered '9 Sep 2020 00:00'	System	15 Sep 2020 19:57:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:50

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:22:44
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	Elisa Moralez (b) (4)	16 Sep 2020 19:03:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	16 Sep 2020 19:02:56
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:02:56
User entered 'Safety Call (Safety Call)'	(b) (4)	
	Elisa Moralez (b) (4)	15 Sep 2020 19:57:29
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:50

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:22:46
User opened query 'Data is required. Please complete.' (Site from System).	Elisa Moralez (b) (4)	16 Sep 2020 19:03:21
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	System	16 Sep 2020 19:02:56
	Elisa Moralez (b) (4)	16 Sep 2020 19:02:56
	(b) (4)	
	Elisa Moralez (b) (4)	15 Sep 2020 19:57:29
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered '9 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	System	15 Sep 2020 20:04:04



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4)	15 Sep 2020 20:04:04

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04



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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:48
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User closed query 'Per multiple query responses on this page site was unable to reach subject and didn't speak to them on 15Spe2020. Please consider removing all fields noted as NONE and instead click assessment not done box.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 01:04:24
Query 'Per multiple query responses on this page site was unable to reach subject and didn't speak to them on 15Spe2020. Please consider removing all fields noted as NONE and instead click assessment not done box.' answered with 'Per source, contact was made on 15-Sep-2020 but it was documented on the 16-Sep-2020 since the Symptom, Temperature, and Oxygen were not reported until late evening(patient did not have access to her thermometer and O2 machine.' (Site from CRA).	Frances Saubon (b) (4)	09 Nov 2020 17:53:26
User opened query 'Per multiple query responses on this page site was unable to reach subject and didn't speak to them on 15Spe2020. Please consider removing all fields noted as NONE and instead click assessment not done box.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:17:54
User entered '0'	Elisa Moralez (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97' reason for change: New Information	Frances Saubon (b) (4)	04 Nov 2020 14:20:48
User entered '90'	Elisa Moralez (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.7' F	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

Nasal Congestion

Audit	User	Time (GMT)
User closed query 'Per source, contact was made. If subject did not answer calls and contact was note made, then the assessment should be Not Done.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:16:46
Query 'Per source, contact was made. If subject did not answer calls and contact was note made, then the assessment should be Not Done.' answered with 'Clarification per previous reply: Contact was made on 15-Sep-2020 but it was documented on the 16-Sep-2020 as information were not reported until late evening. Patient did not have access to their thermometer and O2 machine.' (Site from CRA).	Frances Saubon (b) (4)	04 Nov 2020 19:11:07
User opened query 'Per source, contact was made. If subject did not answer calls and contact was note made, then the assessment should be Not Done.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:52:17
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:52:17
Comment added 'Per source at Day 3, dates are fixed and cough and congestion was reported on 16-Sep-2020, not 14-Sep-2020.'	Frances Saubon (b) (4)	04 Nov 2020 14:19:05
Comment added 'Clarification: Contact not made on 15-Sep-2020 however successful contact was made again on 16-Sep-2020. Source will reflect appropriate data changes. Thank you.'	Frances Saubon (b) (4)	03 Nov 2020 20:00:08
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'Per source, several attempts was made to contact patient but did not answer calls. ' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:49:33
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:13:28
User entered 'None (None)'	Elisa Moralez (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:17:58
Comment added 'Per source at Day 3, dates are fixed and cough and congestion was reported on 16-Sep-2020, not 14-Sep-2020.'	Frances Saubon (b) (4)	04 Nov 2020 14:19:15
Comment added 'Clarification: Contact not made on 15-Sep-2020 however successful contact was made again on 16-Sep-2020. Source will reflect appropriate data changes. Thank you.'	Frances Saubon (b) (4)	03 Nov 2020 20:00:15
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'Per source, several attempts was made to contact patient but did not answer calls. ' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:49:37
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:13:33
User entered 'None (None)'	Elisa Moralez (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:59
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:12:03
User entered '16 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:12:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:11:51
User closed query 'Per source, this was corrected to 96%. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:46:05
Query 'Per source, this was corrected to 96%. Please update.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:42:18
User entered '96' reason for change: Data Entry Error	Frances Saubon (b) (4)	03 Nov 2020 19:42:11
User opened query 'Per source, this was corrected to 96%. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:15:13
User entered '86'	Elisa Moralez (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:12:01
User entered '98.5' F	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:32
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:30
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:33
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:35
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:37
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:38
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:39
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:42
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:11:24
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:11:22
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:42:21
User entered 'Mild (Mild)' reason for change: Per Query Resolution	(b) (4)	03 Nov 2020 19:42:11
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:14:49
User entered 'None (None)'	Elisa Moralez (b) (4)	16 Sep 2020 19:14:44



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:11:26
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:11:25
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:42:24
User entered 'Mild (Mild)' reason for change: Per Query Resolution	(b) (4)	03 Nov 2020 19:42:11
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:14:54
User entered 'None (None)'	Elisa Moralez (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:11:40
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:11:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:11:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:11:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:57:06
User entered 'Day 4 (Day 4)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:28
User entered '17 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:30
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Previous query text was cut off - it should have read: "It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is less than or equal to 93%. Please review and make all appropriate updates."' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:27:03
Query 'Per CDM re-query: Previous query text was cut off - it should have read: "It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is less than or equal to 93%. Please review and make all appropriate updates."' answered with 'DAY 9 IN SOURCE IS ACTUALLY LISTED AS "91.9%" BU AS WE CAN ONLY ENTER 2 DIGITS, IT HAS BEEN ROUNDED TO 92. THIS IS ENTERED CORRECTLY. ALSO IN SOURCE, DAY 10 IS ENTERED AS 93.1% BUT AS WE ARE ONLY ALLOWED TO ENTER 2 DIGITS, IT IS ENTERED AS 93. THIS IS CORRECT PER SOURCE' (Site from DM).	Elisa Moralez (b) (4)	10 Nov 2020 15:31:58
User opened query 'Per CDM re-query: Previous query text was cut off - it should have read: "It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is less than or equal to 93%. Please review and make all appropriate updates."' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:22:58
User closed query 'Per CDM: It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is </=93%. Please review and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:22:58
Query 'Per CDM: It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is </=93%. Please review and make all appropriate updates.' answered with 'On Day 9, patient had 91.9% O2 saturation. It was rounded and recorded in the field as 92% since the entry field on allowed 2 numerical characters. On Day 10, patient had 93.1% O2 saturation and it was recorded as 93% in the entry field due to the same case. Please advise preferred method of recording.' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 18:04:34

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is &lt;=93%. Please review and make all appropriate updates.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 03:21:16
	(b) (4), (b) (6)	07 Nov 2020 04:18:48
User closed query 'Per source, this was 91.9%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:18:40
Query 'Per source, this was 91.9%. Please confirm.' answered with 'Entry box is only allowing to enter 2 numerical digits. Please advise if decimals should be rounded. Thank you.' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:47:19
User opened query 'Per source, this was 91.9%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:21:04
User entered '92'	Frances Saubon (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:49
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:21:43
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:43
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:42
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:41
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:35
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:23:03
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:22:43
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:22:44
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:22:49
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:22:51
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:22:54
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:22:55
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:57:15
Data Entry Error	(b) (4)	
User entered 'Day 5 (Day 5)'	Frances Saubon (b) (4)	21 Sep 2020 20:12:26
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:06
User entered '18 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:08
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 04:19:00
User closed query 'Per source, this was 93.1%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:18:57
Query 'Per source, this was 93.1%. Please confirm.' answered with 'Entry box is only allowing to enter 2 numerical digits. Please advise if decimals should be rounded. Thank you.' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:47:54
User opened query 'Per source, this was 93.1%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:23:15
User entered '93'	Frances Saubon (b) (4)	21 Sep 2020 20:12:26



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:32
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:13
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:11
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:27
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:29
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:33
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:49
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:12
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:13
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:23
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:26
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:28
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:57:23
Data Entry Error	(b) (4)	
User entered 'Day 6 (Day 6)'	Frances Saubon (b) (4)	21 Sep 2020 20:20:53
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:32
User entered '19 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:33
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 04:19:08
User closed query 'Per source, this was 99.1%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:19:07
Query 'Per source, this was 99.1%. Please confirm.' answered with 'Entry box is only allowing to enter 2 numerical digits. Please advise if decimals should be rounded. Thank you.' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:48:04
User opened query 'Per source, this was 99.1%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:27:16
User entered '99'	Frances Saubon (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:44
User entered '97.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 20:28:10
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:45
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:55
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:57
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:46:58
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:05
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:08
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:09
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:11
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:30
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:47:31
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53



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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:57:30
Data Entry Error	(b) (4)	
User entered 'Day 7 (Day 7)'	Frances Saubon (b) (4)	21 Sep 2020 20:23:02
	(b) (4)	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:13
User entered '20 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:15
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:58
User entered '97.6' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:17
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:19
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:20
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:21
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:23
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:34
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:35
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:38
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:41
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:42
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:46
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:48:49
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:57:40
Data Entry Error	(b) (4)	
User entered 'Day 8 (Day 8)'	Frances Saubon (b) (4)	21 Sep 2020 20:24:37
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '21 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '99'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:57:51
User entered 'Day 9 (Day 9)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '22 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '97'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:57:59
User entered 'Day 10 (Day 10)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '23 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '94'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:58:12
Data Entry Error	(b) (4)	
User entered 'Day 11 (Day 11)'	Frances Saubon (b) (4)	24 Sep 2020 21:28:55
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:24
User entered '24 Sep 2020'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:55
User entered '0'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

**US3322006**

**Folder: Covid-19 Assessment 14 Sep 2020**

**Form: Symptom Log (11)**

**Generated On: 26 Nov 2020 10:57:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:26
User entered '97.1' F	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:28
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:29
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:31
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:32
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:34
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:39
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:40
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:42
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:51
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:45
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:56:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:58:20
Data Entry Error	(b) (4)	
User entered 'Day 12 (Day 12)'	Frances Saubon (b) (4)	25 Sep 2020 23:02:00
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:19
User entered '25 Sep 2020'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:20
User entered '0'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:44
User entered '97.7' F	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:45
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:51
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:54
User entered 'None (None)'	Frances Saubon (b) (4)	25 Sep 2020 23:02:00
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:58
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:43:59
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:44:00
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:44:02
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:44:03
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:44:09
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:44:10
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:44:12
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:58:35
Data Entry Error	(b) (4)	
User entered 'Day 13 (Day 13)'	Frances Saubon (b) (4)	28 Sep 2020 20:52:23
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 20:28:43
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:58:43
Data Entry Error	(b) (4)	
User entered 'Day 14 (Day 14)'	Frances Saubon (b) (4)	28 Sep 2020 20:55:11
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:21
User entered '27 Sep 2020'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:29
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:23
User entered '96.9' F	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:31
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:33
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:34
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:38
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:40
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
	(b) (4)	
User entered 'Mild (Mild)' reason for change: New Information	Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:42
User entered 'None (None)'	Frances Saubon (b) (4)	28 Sep 2020 20:55:11
	(b) (4)	



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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:46
User entered 'None (None)'	Frances Saubon (b) (4)	28 Sep 2020 20:55:11
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:53
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:55
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:57
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)' reason for change:	Elisa Moralez (b) (4)	28 Sep 2020 21:58:52
Data Entry Error	(b) (4)	
User entered 'Day 15 (Day 15)'	Frances Saubon (b) (4)	28 Sep 2020 21:03:49
	(b) (4)	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '28 Sep 2020'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '99'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '97.3' F	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
	(b) (4)	
User entered 'Mild (Mild)' reason for change: New Information	Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4)	28 Sep 2020 21:03:49
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4)	28 Sep 2020 21:03:49
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

Fatigue

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:26:44
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08OCT2020. Please reconcile or clarify.' answered with 'Per source on Day 15th 28-Sep-2020, all the symptoms are resolved. Please clarify.' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 18:17:17
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:22:49
User entered '14 Sep 2020'	Elisa Moralez (b) (4)	28 Sep 2020 21:56:29



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29



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Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29



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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

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[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:57:50

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

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Form: COVID Diagnostic Test

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[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 14:47:24
User entered '14 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4)	16 Sep 2020 19:03:49
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:03:46
User entered '14 Sep 2020'	Elisa Moralez (b) (4)	15 Sep 2020 20:05:50
	(b) (4)	

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Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:57:50

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 14:47:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Morales (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4)	16 Sep 2020 19:03:53
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Morales (b) (4)	16 Sep 2020 19:03:46
User entered 'Yes (Y)'	Elisa Morales (b) (4)	15 Sep 2020 20:05:50

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Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:57:50

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
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)	21 Sep 2020 06:17:08
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 'Test was positive. Data has been updated on AE form' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 23:28:54
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	18 Sep 2020 23:28:18
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Sep 2020 23:28:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 14:47:39
Query 'Data is required. Please complete.' answered with 'TEST RESULTS NOT YET RETURNED' (Site from System).	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:08:19
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 20:05:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

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Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:57:50

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 14:47:46
User entered '14 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4)	16 Sep 2020 19:03:57
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:03:46
User entered '14 Sep 2020'	Elisa Moralez (b) (4)	15 Sep 2020 20:05:50
	(b) (4)	



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Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 14:47:48
User entered 'Other (Other)' reason for change: Data Entry Error	Elisa Morales (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4)	16 Sep 2020 19:04:00
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Morales (b) (4)	16 Sep 2020 19:03:46
User entered 'Other (Other)'	Elisa Morales (b) (4)	15 Sep 2020 20:05:50

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Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User entered 'nasopharyngeal swab and blood' reason for change: Data Entry Error	Elisa Morales (b) (4) (b) (4)	16 Sep 2020 19:15:31
User entered empty; reason for change Data Entry Error	Elisa Morales (b) (4) (b) (4)	16 Sep 2020 19:03:46
User entered 'NASOPHARYNGEAL AND BLOOD'	Elisa Morales (b) (4) (b) (4)	15 Sep 2020 20:05:50

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 14:47:51
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4)	16 Sep 2020 19:04:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:03:46
User entered 'No (N)'	Elisa Moralez (b) (4)	15 Sep 2020 20:05:50

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

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[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 19:59:02
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 23:28:18

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Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10



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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
User closed query 'Per source, subject reported O2 saturations of 90-93% on 15Sep20, 17-18Sep20. Please update.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	07 Nov 2020 19:24:28
Comment added 'O2 Saturation for 17-Sep-2020 was 91.9% however entry field only allows 2 numerical digits therefore "91" was recorded.' DataPoint Un-verified.	(b) (4), (b) (6) Frances Saubon (b) (4) (b) (4)	04 Nov 2020 20:51:40 04 Nov 2020 14:34:59
User entered 'Yes (Y)' reason for change: Per Query Resolution Query 'Per source, subject reported O2 saturations of 90-93% on 15Sep20, 17-18Sep20. Please update.' answered with 'Source data has been updated and O2 saturation on the mentioned dates are as follows: 15-Sep-2020, 97%; 16-Sep-2020, 96%; 17-Sep-2020, 91.9%; 18-Sep-2020, 93.1%. O2 saturation for 17-Sep-2020 will be listed in this field as it is ≤ 93%.' (Site from CRA).	Frances Saubon (b) (4) (b) (4) Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23 04 Nov 2020 14:33:23 04 Nov 2020 14:32:25
User opened query 'Per source, subject reported O2 saturations of 90-93% on 15Sep20, 17-18Sep20. Please update.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Nov 2020 19:47:32 02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23
User entered '17 Sep 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10



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[End Date](#)

Audit	User	Time (GMT)
Query 'Please verify as symptom log notes last day <= 93% was on 18Sep2020' canceled (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:24:52
User opened query 'Please verify as symptom log notes last day <= 93% was on 18Sep2020' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:20:56
DataPoint Un-verified.	Frances Saubon (b) (4)	04 Nov 2020 14:33:23
User entered '17 Sep 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4)	04 Nov 2020 14:33:23
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23
User entered '91' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	



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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10



US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:57:50

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:57:50

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:04:02
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:04:19
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Sep 2020 18:19:07

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:57:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:09:50

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:57:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:09:50

**US3322006**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:09:50

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:57:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:10:35

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:57:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:10:35

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:57:50

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:10:35



US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:57:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:11:04

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:57:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:11:04

**US3322006**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:11:04

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:57:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:57:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

**US3322006**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:57:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:57:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	28 Sep 2020 21:19:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:18:57
Query 'Data is required. Please complete.' answered with 'Day 14 has not been completed yet, will enter once completed' (Site from System).	Frances Saubon (b) (4)	24 Sep 2020 21:31:08
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:30:42
User entered empty.	Frances Saubon (b) (4)	24 Sep 2020 21:30:42



**US3322006**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	28 Sep 2020 21:19:16
User entered empty.	Frances Saubon (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:57:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:57:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	21 Oct 2020 15:24:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Day 21 has not been completed yet, will enter once completed' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:18:59
User opened query 'Data is required. Please complete.' (Site from System).	Frances Saubon (b) (4)	24 Sep 2020 21:31:14
User entered empty.	(b) (4)	
	System	24 Sep 2020 21:30:42
	Frances Saubon (b) (4)	24 Sep 2020 21:30:42
	(b) (4)	

**US3322006**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 20:33:35
User entered '6 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 15:24:21
User entered empty.	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:57:50

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:57:50

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	21 Oct 2020 15:24:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'Day 28 has not been completed yet, will enter once completed' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:19:02
User opened query 'Data is required. Please complete.' (Site from System).	Frances Saubon (b) (4)	24 Sep 2020 21:31:21
User entered empty.	(b) (4)	
	System	24 Sep 2020 21:30:42
	Frances Saubon (b) (4)	24 Sep 2020 21:30:42
	(b) (4)	

**US3322006**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 15:24:38
User entered empty.	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:07:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:29:31



US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:07:44
User entered '14 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:07:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Sep 2020 23:29:31

**US3322006**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:39
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:41
User entered '14 Sep 2020'	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
	(b) (4)	

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 17:48:32
User closed query 'Per source, it states that the time of assessment is 14:15 vs 14:30. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:48:30
Query 'Per source, it states that the time of assessment is 14:15 vs 14:30. Please confirm and update accordingly.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	02 Nov 2020 21:19:48
User entered '14:15' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	02 Nov 2020 21:19:42
User opened query 'Per source, it states that the time of assessment is 14:15 vs 14:30. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 20:11:35
User entered '14:30'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

**US3322006**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:15'	System	02 Nov 2020 21:19:42
User entered '14 Sep 2020 14:30'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:43
User entered '67' in	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
DataPoint set to visible.	(b) (4) System	18 Sep 2020 23:29:31



US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:45
User entered '256.6' lb	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
DataPoint set to visible.	(b) (4) System	18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:46
User entered '97.2' F	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
	(b) (4)	

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:50
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:52
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
	(b) (4)	

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:54
User entered '91'	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
	(b) (4)	

**US3322006**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:55
User entered '18'	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
	(b) (4)	

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 19:07:42



US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:11:58
User closed query 'Per ETRTR: Please confirm clinical significance on high blood pressure and consider reporting if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 03:55:00
Query 'Per ETRTR: Please confirm clinical significance on high blood pressure and consider reporting if applicable, thanks.' answered with 'ncs' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 14:34:17
User opened query 'Per ETRTR: Please confirm clinical significance on high blood pressure and consider reporting if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 14:30:16
User entered '132'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:12:02
User entered '95'	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
	(b) (4)	

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:12:11
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:08:02

US3322006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:12:11
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:08:02

US3322006

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:57:50

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:12:37
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:08:30

US3322006

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:57:50

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:12:37
User entered '14 Sep 2020'	Frances Saubon (b) (4)	21 Sep 2020 19:08:30
	(b) (4)	



US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:13:36
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' ' answered with 'Corrected' (Site from DM).	Frances Saubon (b) (4)	30 Oct 2020 15:49:43
User entered '08 Oct 2020' reason for change: Per Query Resolution	(b) (4)	30 Oct 2020 15:49:22
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:42:23
User entered '8 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:17:52

**US3322006**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:57:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:42:47
Query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' answered with 'Date updated per query' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 19:57:14
User entered '08 Oct 2020' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 19:57:05
User opened query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:10:17
User entered '8 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '13:30'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

**US3322006**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '08 Oct 2020 13:30'	System	09 Nov 2020 19:57:05
User entered '8 Oct 2020 13:30'	System	21 Oct 2020 13:18:47



US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Height (xxx.x)

Audit	User	Time (GMT)
User entered '67' in	Elisa Moralez (b) (4)	21 Oct 2020 13:18:47
DataPoint set to visible.	(b) (4) System	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '255' lb	Elisa Moralez (b) (4)	21 Oct 2020 13:18:47
DataPoint set to visible.	(b) (4) System	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '69'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

**US3322006**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:57:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

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

Audit	User	Time (GMT)
User entered '17'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47



US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '150'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 07:08:11
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Elisa Moralez (b) (4)	21 Oct 2020 13:18:58
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		21 Oct 2020 13:18:47
User entered '104'	Elisa Moralez (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:19:12

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:50

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:19:12

US3322006

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:57:50

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 08OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:36:44
Query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 08OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Please note that a DCF has been submitted. Thank you.' (Site from DM).	Frances Saubon (b) (4)	28 Oct 2020 13:35:29
User opened query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 08OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:15:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Oct 2020 13:19:21



US3322006

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:57:50

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:19:21

US3322006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 18:42:14

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:42
User entered 'USA-US060-2020-mRNA-1273-P301000003'	System	20 Sep 2020 18:19:37
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 18:19:37

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:51:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:51:52
Data point term sent to Coder	System	29 Sep 2020 19:13:04
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 19:12:48
User entered 'Symptomatic Covid -19' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 19:12:48
User closed query 'PV Query: Please consider updating event term to COVID-19 infection, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 16:42:51
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:26:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:26:47
Data point term sent to Coder	System	28 Sep 2020 20:25:24
Query 'PV Query: Please consider updating event term to COVID-19 infection, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 20:25:21
Coding entries removed.	(b) (4), (b) (6)	28 Sep 2020 20:25:14
User entered 'COVID-19 infection' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 20:25:14
User opened query 'PV Query: Please consider updating event term to COVID-19 infection, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:17:24
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:15:47

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	19 Sep 2020 05:15:47  18 Sep 2020 23:27:34
User entered 'Confirmed, positive COVID-19 case'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:38:47
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' answered with 'UPDATED. THIS IS NOT A SOLICITED ADVERSE REACTION' (Site from DM).	Blessing Felix-Okoroji (b) (4)	20 Oct 2020 14:42:06
User entered 'No (N)' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	20 Oct 2020 14:41:45
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:13:04
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:03:52
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:03:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16



US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:02:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 15:23:23
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 Oct 2020 19:02:38
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 Oct 2020 19:02:38
User entered '6 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4)	06 Oct 2020 19:02:38
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 Oct 2020 19:02:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' answered with 'Noted, this field will be updated once end date is available. Thank you.' (Site from Safety).	Frances Saubon (b) (4)	06 Oct 2020 13:17:28
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 19:08:52
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' canceled (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 21:50:20
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:16:16
User entered empty.	System	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16



US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16



US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:22:56
Comment added 'Entry is correct, subject discontinued from treatment due to COVID-19 positive test per sponsor instructions. This is not related to IP.'	Frances Saubon (b) (4)	21 Sep 2020 16:07:37
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	18 Sep 2020 23:27:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:59:28
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 06:53:57
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'will finish final forms upon completion of all followup illness telehealth visits' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:47:40
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'covid positive test is reason for dosing discontinuation' (Site from System).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:47:20
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:46:31
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:55:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PEr CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "symptomatic Covid 19". Please review and update or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:21:54
Query 'PEr CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "symptomatic Covid 19". Please review and update or update accordingly. ' answered with 'will update per updated source immediately, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:37:43
User opened query 'PEr CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "symptomatic Covid 19". Please review and update or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:10:46
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 23:27:16



US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 15:23:29
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data updated today in source, promptly entered here, thank you!' (Site from Safety).	Elisa Moralez (b) (4)	06 Oct 2020 19:02:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4)	06 Oct 2020 19:02:19
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 19:08:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 21:50:24
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:16:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:50

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 16:43:03
User closed query 'PV Query: Did the subject require oxygen for hypoxia?' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 16:42:59
Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'none' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 20:39:02
Query 'PV Query: Did the subject require oxygen for hypoxia?' answered with 'no' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 20:38:57
User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:17:04
User opened query 'PV Query: Did the subject require oxygen for hypoxia?' (Site from Safety).	(b) (4), (b) (6)	25 Sep 2020 17:16:51
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 23:27:16

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:37:58
Comment added 'CLARIFICATION: Information has been changed back to Hematochezia as per source. Subject's episode of hematochezia was due to a pre existing diagnosis of hemorrhoids with a prior episode reported about 10 years ago in 2010. Please see updated Medhx.'	Frances Saubon (b) (4)	16 Nov 2020 20:38:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Haematochezia, LLT: Hematochezia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:37:47
Data point term sent to Coder	System	16 Nov 2020 20:37:24
Coding entries removed.	Frances Saubon (b) (4)	16 Nov 2020 20:37:18
User entered 'Hematochezia' reason for change: New Information	Frances Saubon (b) (4)	16 Nov 2020 20:37:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:26:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:26:47
Data point term sent to Coder	System	16 Nov 2020 20:26:08
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' answered with 'updated per corrected source' (Site from DM).	Elisa Moralez (b) (4)	16 Nov 2020 20:25:48
Coding entries removed.	Elisa Moralez (b) (4)	16 Nov 2020 20:25:38

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'hemorrhoids' reason for change: New Information	Elisa Moralez (b) (4)	16 Nov 2020 20:25:38
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. '(Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 09:46:46
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Haematochezia, LLT: Hematochezia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:56:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:56:36
Data point term sent to Coder	System	21 Oct 2020 14:55:47
User entered 'Hematochezia'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13



US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13



**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13



US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13



US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[None](#)

Audit	User	Time (GMT)
User entered '1'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:55:13

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:55:13



**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:59:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:59:32
Data point term sent to Coder	System	21 Oct 2020 14:58:53
User entered 'Elevated Blood Pressure'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Oct 2020'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:57:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:58:07



US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:57:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07



US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07



US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:57:50**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07



US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:57:50

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:58:07

**US3322006**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:58:07

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:57:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please add Medication dosed for COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:00:22
Query 'Per ETRTR: Please add Medication dosed for COVID-19, thanks.' answered with 'all medications in source are entered' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 17:36:11
User opened query 'Per ETRTR: Please add Medication dosed for COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 14:26:05
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	24 Aug 2020 16:25:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:28:51

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

Name of Medication

Audit	User	Time (GMT)
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 SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:06:45
Data point term sent to Coder	System	29 Oct 2020 20:05:25
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 20:05:07
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 SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 07:37:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 07:37:44
Data point term sent to Coder	System	25 Sep 2020 13:32:28
User closed query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	25 Sep 2020 13:32:07
Query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'information clarified by CRC, thank you' (Site from System).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:32:07
User entered 'albuterol sulfate' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 13:31:51

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. (Site from System).	Coder Import (b) (4)	23 Sep 2020 10:10:45
Data point term sent to Coder	System	22 Sep 2020 20:20:27
User entered 'Proair'	Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:32:54
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	21 Oct 2020 21:23:37
User entered '90' reason for change: Per Query Resolution	(b) (4)	21 Oct 2020 21:23:25
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:05:20
User entered '2'	Frances Saubon (b) (4)	22 Sep 2020 20:20:11

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Oct 2020 21:23:25
User entered 'puff (PUFF)'	Frances Saubon (b) (4)	22 Sep 2020 20:20:11

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Per Query Resolution	Elisa Moralez (b) (4)	29 Oct 2020 20:05:07
User entered 'Other (OTHER)'	Frances Saubon (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

If route of administration is Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review the route of administration for this medication as "Respiratory (Inhalation)" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:52:26
Query 'Per CDM: Please review the route of administration for this medication as "Respiratory (Inhalation)" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 20:05:11
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 20:05:07
User opened query 'Per CDM: Please review the route of administration for this medication as "Respiratory (Inhalation)" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:15:36
Query 'Per CDM: Please review the route of administration for this medication as "Inhalation" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:15:12
User opened query 'Per CDM: Please review the route of administration for this medication as "Inhalation" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:14:53
User entered 'inhalation'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:20:11

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:20:11

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:04:38
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 Nov 2020 20:04:38
Data point term sent to Coder	System	09 Nov 2020 16:22:49
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:22:32
User entered 'Aspirin (NSAID*) 845mg/Caffeine 65 mg(BC Powder)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:22:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BC HEADACHE [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
Data point term sent to Coder	System	22 Sep 2020 20:22:30
User entered 'Aspirin (BC powder)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

[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. If the HEADACHE 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 or 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 HEADACHE did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:16:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE 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 or 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 HEADACHE did not meet the AE reporting criteria' answered with 'Intermittent tension headaches is in MH, please clarify ' (Site from DM).	Frances Saubon (b) (4)	21 Oct 2020 15:04:41
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE 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 or 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 HEADACHE did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:16:34
User entered 'Intermittent Tension Headaches'	Frances Saubon (b) (4)	22 Sep 2020 20:22:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:44:38
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 16:22:37
User entered '845/65' reason for change: Per Query Resolution	(b) (4)	09 Nov 2020 16:22:32
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:41:18
User entered '845'	Frances Saubon (b) (4)	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:50

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'UN Jan 2019'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:22:22

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:22:22



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:05:39
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 Nov 2020 20:05:39
Data point term sent to Coder	System	09 Nov 2020 16:23:50
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:23:01
User entered 'Aspirin (NSAID*) 845mg/Caffeine 65 mg(BC Powder)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:23:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BC HEADACHE [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
Data point term sent to Coder	System	22 Sep 2020 20:23:31
User entered 'Aspirin (BC Powder)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Migraine Headaches'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:44:56
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 16:23:09
User entered '845/65' reason for change: Per Query Resolution	(b) (4)	09 Nov 2020 16:23:01
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:41:37
User entered '845'	Frances Saubon (b) (4)	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24



**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:24

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:19:40
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 Nov 2020 20:19:40
Data point term sent to Coder Coding entries removed.	System Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:25:51 09 Nov 2020 16:24:57
User entered 'Aspirin (NSAID*) 845 mg/Caffeine 65 mg(BC Powder)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:24:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BC HEADACHE [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:55:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:55:40
Data point term sent to Coder	System	22 Sep 2020 20:24:34
User entered 'Aspirin (BC Powder)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the eDiary CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:00:53
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the eDiary CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Corrected. Medication was not taken prophylactically. ' (Site from DM).	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 15:03:06
User entered 'No (N)' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 15:02:45
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the eDiary CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:42:25
User entered 'Yes (Y)'	Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

[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 timeframe. If the HEADACHE 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 HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 14:20:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE 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 HEADACHE did not meet the AE reporting criteria.' answered with 'Per protocol ARs that start and stop during the 7 days post dose e-diary are recorded by the e-diary and do not need to be entered in CRF as a separate entry.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 15:04:38
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE 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 HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:42:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:45:10
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 16:25:03
User entered '845/65' reason for change: Per Query Resolution	Frances Saubon (b) (4)	09 Nov 2020 16:24:57
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:42:34
User entered '845'	Frances Saubon (b) (4)	22 Sep 2020 20:24:29



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '22 Aug 2020'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '23 Aug 2020'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:24:29

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:24:29

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:57:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:57:08
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	17 Nov 2020 16:00:34
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' answered with 'Per source, Seasonal allergies were not worsening' (Site from DM).	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 20:36:38
Data point term sent to Coder	System	11 Nov 2020 23:01:33
Coding entries removed.	Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54
User entered 'Loratadine (CLARITIN)' reason for change: New Information	Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 16:26:35

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:26:35  09 Nov 2020 16:25:53 09 Nov 2020 16:25:32
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:43:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:39:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Claritin'	Coder Import (b) (4) (b) (4) System Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:33  22 Oct 2020 14:39:00 22 Oct 2020 14:38:32



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:48:10
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 16:25:40
User entered 'Seasonal Allergies' reason for change: Per Query Resolution	(b) (4)	09 Nov 2020 16:25:32
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:43:31
User entered 'Allergies'	Elisa Moralez (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10' reason for change: New Information	Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54
User entered '1'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54
User entered 'tablet (TABLET)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:38:32

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:38:32



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: OTHER OPHTHALMOLOGICALS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:25:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:25:54
Data point term sent to Coder	System	24 Nov 2020 16:05:39
User closed query 'CDM-Coding, if unknown the ingredients please add 'Unknown' to the term in bracket.' (Site from System).	System	24 Nov 2020 16:04:57
Query 'CDM-Coding, if unknown the ingredients please add 'Unknown' to the term in bracket.' answered with 'term changed per query resolution' (Site from System).	Frances Saubon (b) (4) (b) (4)	24 Nov 2020 16:04:57
User entered 'ANTI HISTAMINE EYE DROPS [unknown]' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	24 Nov 2020 16:04:42
User opened query 'CDM-Coding, if unknown the ingredients please add 'Unknown' to the term in bracket.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 01:55:01
Data point term sent to Coder	System	12 Nov 2020 14:51:05
Data point term sent to Coder	System	09 Nov 2020 16:30:59
User closed query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:12:02
Query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' answered with 'Please see last reply. The subject does not remember the name of the eye drops that they took. Thank you' (Site from DM).	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 14:37:35
User opened query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:38:45

v6.020 DTW (1102)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	23 Oct 2020 15:20:30
User closed query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	System	23 Oct 2020 15:19:52
Query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' answered with 'Patient does not remember medication name or active ingredients. Other common medications of this type have the ingredients "Naphazoline HCl and Pheniramine Maleate" but we are not sure that this is what the patient used. Should we update with this information or take other action? Please advise, thank you.' (Site from System).	Elisa Moralez (b) (4)	23 Oct 2020 15:19:52
User opened query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	23 Oct 2020 08:36:26
Data point term sent to Coder	System	22 Oct 2020 14:40:01
User entered 'Antihistamine Eye Drops'	Elisa Moralez (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:50:20
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 16:30:47
User entered 'SEASONAL ALLERGIES' reason for change: Per Query Resolution	(b) (4)	09 Nov 2020 16:30:41
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:40:27
User entered 'Allergies'	Elisa Moralez (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'drops'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 17:53:57
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated per changed source' (Site from DM).	Elisa Moralez (b) (4)	12 Nov 2020 14:51:09
User entered 'Topical (TOPICAL)' reason for change: New Information	(b) (4)	12 Nov 2020 14:50:52
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:40:37
User entered 'Intraocular (INTRAOCULAR)'	Elisa Moralez (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:50

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:39:06

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:39:06

**US3322006**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:57:50

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: NYQUIL SEVERE COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:12:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:12:24
Data point term sent to Coder	System	22 Oct 2020 14:42:06
User entered 'Nyquil [Acetaminophen, Dextromethorphan hydrobromide, Doxylamine succinate Phenylephrine hydrochloride]'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:57:50

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Indication](#)

Audit	User	Time (GMT)
User entered 'symptomatic COVID-19'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '650/20/12.5/10'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04



US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:57:50

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

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

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04



US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:57:50

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 10:57:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:42:04

US3322006

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:57:50**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:29:17

US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:50

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:46:31



US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:50

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:28:05
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'subject is still participating in the study for follow up.' (Site from DM).	Frances Saubon (b) (4)	30 Sep 2020 14:34:34
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:27:48
User entered 'Due to SARS-COV-2 (COVID)'	Elisa Moralez (b) (4)	23 Sep 2020 20:46:31

US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:50

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:46:31

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37



US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37



US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37



US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37



US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
User entered '20/Sep/2020 14:20'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:57:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:43:15
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37



**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37



**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
User entered '29/Sep/2020 12:43'	System	29 Sep 2020 16:43:23

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:57:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:25:00
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 16:43:23

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37



**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37



**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 26 Nov 2020 10:57:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
User entered '07/Oct/2020 13:25'	System	07 Oct 2020 13:25:11

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:57:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 15:23:39
User entered 'I'	(b) (4), (b) (6)	07 Oct 2020 13:25:11



**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37



US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

**US3322006**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:57:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06