

US3322061 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:59:27

All time stamps listed in this document are displayed in GMT



**US3322061**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:59:27**

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[Participant ID](#)

US3322061

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

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US3322061

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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 10:59:27

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

Date of Informed Consent ( <i>dd MMM yyyy</i> )	20 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 10:59:27

Did the participant meet all eligibility criteria?

Yes ☒

No ☐



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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:27

Were any significant conditions reported?

Yes ☒

No ☐



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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:27

Condition	MIGRAINE
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:27

Condition	LEFT KNEE ARTHROSCOPY
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992



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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:27

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999



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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:27

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001



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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:27

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001



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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:27

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



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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:27

Condition	BREAST AUGMENTATION
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004



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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:27

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1967
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 1967
Start Year (derived)	1967
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:27

Condition	BAND-AIDS ALLERGY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:59:27

Condition	SHELLFISH ALLERGY
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:59:27

Condition	HOT FLASHES
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:59:27

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:59:27

Condition	LEFT KNEE TORN MENISCUS
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992



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Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:59:27

Condition	ABDOMINOPLASTY
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004



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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:48 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:48
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	154.4 lb
BMI ( <i>xxx.x</i> )	24.97292 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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 10:59:27

Date of assessment ( <i>dd MMM yyyy</i> )	20 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 type="radio"/>
	Post-menopausal <input checked="" 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> ) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> )	UN UNK 2008
Date of last menstruation unknown	False



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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify**



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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

(b) (6)

RETIRED, BUT SEES 10-25  
PATIENTS ONE DAY PER WEEK

AROUND 40 PEOPLE AT A TIME  
FOR WORK

ABOUT 2X PER MONTH  
TRAVELS,

**Location and Living Circumstances Risk (check all that apply)**

<b>No Risk Identified</b>	False
<b>Resides in Nursing Home or Assisted Living Facility</b>	False
<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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 10:59:27

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 106726

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 ☒



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 10:59:27**

Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	8:48 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 8:48
Temperature (xxx.x)	97.0 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 12:15
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Was the physical examination performed?

Yes ☐  
No ☒

Date of examination (dd MMM yyyy)

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



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 11:42 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 11:42

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 10:59:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	21 AUG 2020
Collection time ( <i>00:00-23:59</i> )	11:30 (24 HR)
Collection date and time (derived)	21 AUG 2020 11:30



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:27

Collection date ( <i>dd MMM yyyy</i> )			21 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	11:26	21 AUG 2020 11:26
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

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 10:59:27

**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

21 AUG 2020 12:15

PC Open Date & Time

21 AUG 2020 12:02

PC Close Date & Time

21 AUG 2020 14:32



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °F

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

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

PC Time Stamp	21 AUG 2020 22:29
PC Open Date & Time	21 AUG 2020 15:27
PC Close Date & Time	22 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:27

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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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 23:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:27

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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.

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

23 AUG 2020 19:44

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:27

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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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 18:53

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 18:13

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:27

---

**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):

PC Time Stamp

26 AUG 2020 21:13

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:27

---

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 20:53

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

**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

21 AUG 2020 12:15

PC Open Date & Time

21 AUG 2020 12:02

PC Close Date & Time

21 AUG 2020 14:32



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

**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

21 AUG 2020 22:29

PC Open Date & Time

21 AUG 2020 15:27

PC Close Date & Time

22 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:27

**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

22 AUG 2020 23:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:27

**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

23 AUG 2020 19:44

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:27

**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

24 AUG 2020 18:53

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:27

**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

25 AUG 2020 18:14

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:27

**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

26 AUG 2020 21:13

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:27

**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

27 AUG 2020 20:52

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

**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 ☐



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 12:16
PC Open Date & Time	21 AUG 2020 12:02
PC Close Date & Time	21 AUG 2020 14:32



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

**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 ☐



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 22:29
PC Open Date & Time	21 AUG 2020 15:27
PC Close Date & Time	22 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:27

**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 ☒



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:27

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 23:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:27

**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 ☒



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:27

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 19:44
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:27

**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 ☒



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:27

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:53
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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 ☒



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:27

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 18:14
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:27

**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 ☒



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:27

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 21:13
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:27

**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 ☒



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:27

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:52
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:59:27

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 AUG 2020 20:29
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(8)

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 8

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 28 AUG 2020 20:26

PC Open Date and Time 28 AUG 2020 12:00

PC Close Date and Time 29 AUG 2020 11:59



US3322061

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 9

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 29 AUG 2020 20:29

PC Open Date and Time 29 AUG 2020 12:00

PC Close Date and Time 30 AUG 2020 11:59



US3322061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

Was Contact Attempted?

Yes ☒

No ☐

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

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

3 UNSUCCESSFUL ATTEMPT TO  
CONTACT SUBJECT

*If Contact Not Made, please provide Comments*



US3322061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

Was Contact Attempted?

Yes ☒

No ☐

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

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3322061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

Was Contact Attempted?

Yes ☒

No ☐

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

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3322061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3322061**

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

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:27**

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 \_\_\_\_\_



US3322061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

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	



US3322061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

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	



US3322061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

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.*



US3322061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

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? \_\_\_\_\_



US3322061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:27

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

Collection date ( <i>dd MMM yyyy</i> )	<hr/>
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Collection time ( <i>00:00-23:59</i> )	<hr/>
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Collection date and time (derived)	<hr/>
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**US3322061**

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

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 26 Nov 2020 10:59:27**

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			



**US3322061**

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

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:27**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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22 OCT 2020 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 OCT 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2020 23:59
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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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08 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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12 NOV 2020 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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10 DEC 2020 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 DEC 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 187

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

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

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

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

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

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

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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07 MAR 2021 00:01

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11 MAR 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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18 MAR 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 215

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

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

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

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

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

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

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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25 MAR 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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01 APR 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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18 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 APR 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

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29 APR 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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06 MAY 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 334

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

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

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

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

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 NOV 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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02 JAN 2022 00:01

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06 JAN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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09 JAN 2022 00:01

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13 JAN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 516

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

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

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

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

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

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



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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20 JAN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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27 JAN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



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

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

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03 FEB 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



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**Generated On: 26 Nov 2020 10:59:27**

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

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10 FEB 2022 23:59



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

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

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17 FEB 2022 23:59



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



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

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

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

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24 FEB 2022 23:59



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

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

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

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03 MAR 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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06 MAR 2022 00:01

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10 MAR 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

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**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



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

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24 MAR 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAR 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

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14 APR 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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05 JUN 2022 00:01

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09 JUN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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16 JUN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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 <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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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="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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

**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 ☐



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:27

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"/>



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

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

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

Date of Contact	11 SEP 2020
Time of Contact	00:00
Date and Time of Contact (derived)	11 SEP 2020 00:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="radio"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

	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	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	299 of 2030	



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

	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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

	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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

	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	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	303 of 2030	



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

	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)

Generated On: 26 Nov 2020 10:59:27

	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 (3)

Generated On: 26 Nov 2020 10:59:27

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 10:59:27

	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	97 %	
O2 Saturation Units	%	
Temperature	97.5 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 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)	307 of 2030	



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Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

	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 (3)

Generated On: 26 Nov 2020 10:59:27

	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 (4)

Generated On: 26 Nov 2020 10:59:27

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 10:59:27

	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	98 %	
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)	311 of 2030	



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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

	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 (4)

Generated On: 26 Nov 2020 10:59:27

	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 (5)

Generated On: 26 Nov 2020 10:59:27

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 10:59:27

	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	98 %	
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)	315 of 2030	



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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

	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 (5)

Generated On: 26 Nov 2020 10:59:27

	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 (6)

Generated On: 26 Nov 2020 10:59:27

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 10:59:27

	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	100 %	
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)	319 of 2030	



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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

	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)

Generated On: 26 Nov 2020 10:59:27

	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 (7)

Generated On: 26 Nov 2020 10:59:27

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"/>



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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	323 of 2030	



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



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Form: Symptom Log (7)

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	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" 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 (8)

Generated On: 26 Nov 2020 10:59:27

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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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

	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	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)	327 of 2030	



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Form: Symptom Log (8)

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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 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 10:59:27

	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)

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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 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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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

	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	98 %	
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)	331 of 2030	



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Form: Symptom Log (9)

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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 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 10:59:27

	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 (10)

Generated On: 26 Nov 2020 10:59:27

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 (10)

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	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	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	335 of 2030	



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Form: Symptom Log (10)

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



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Form: Symptom Log (10)

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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 (11)

Generated On: 26 Nov 2020 10:59:27

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 (11)

Generated On: 26 Nov 2020 10:59:27

	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"/>
v6.020 DTW (1102)	339 of 2030	



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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 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 (11)

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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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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

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 (12)

Generated On: 26 Nov 2020 10:59:27

	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	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)	343 of 2030	



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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

	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 (12)

Generated On: 26 Nov 2020 10:59:27

	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 (13)

Generated On: 26 Nov 2020 10:59:27

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 (13)

Generated On: 26 Nov 2020 10:59:27

	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	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)	347 of 2030	



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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

	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 (13)

Generated On: 26 Nov 2020 10:59:27

	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 (17)

Generated On: 26 Nov 2020 10:59:27

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 (17)

Generated On: 26 Nov 2020 10:59:27

	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	97.2 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)	351 of 2030	



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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

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

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

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

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

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

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

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



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Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

	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 (18)

Generated On: 26 Nov 2020 10:59:27

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 (18)

Generated On: 26 Nov 2020 10:59:27

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 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)	355 of 2030	



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Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

	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 10:59:27

	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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Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

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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Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

	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)	359 of 2030	



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Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

	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 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

	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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

	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)	363 of 2030	



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

	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 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

	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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[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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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

	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)	367 of 2030	



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

	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"/>



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

	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 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

Date of Visit	11 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	11 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below _____	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

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 \_\_\_\_\_

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

Oxygen Saturation \_\_\_\_\_

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 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

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



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

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 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:59:27

---

[Generate Next COVID-19 Assessment](#)

Yes ☐  
No ☒

---



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Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

Date of Contact	14 OCT 2020
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>



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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input 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 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

	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	
Assessment Not Done	
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"/>
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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

	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 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

	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 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

Date of Visit	14 OCT 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	14 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0



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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:59:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 SEP 2020
Day 5	Yes	16 SEP 2020
Day 7	Yes	17 SEP 2020
Day 9	Yes	20 SEP 2020
Day 14	No	
Day 21	No	
Day 28	Yes	14 OCT 2020



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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1



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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	16:30 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 16:30
Height ( <i>xxx.x</i> )	66.0 in
Weight ( <i>xxx.x</i> )	145.0 lb
Temperature ( <i>xxx.x</i> )	96.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 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 10:59:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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



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Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:59:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 SEP 2020



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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

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



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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	14:42 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 14:42
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	150 lb
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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



US3322061

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:59:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 OCT 2020



US3322061

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:27

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

AEID	USA-US060-2020-MRNA-1273-P30 1000002
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)	07 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)	15 SEP 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	
v6.020 DTW (1102)	391 of 2030



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

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)	_____



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

AEID

Adverse event

AXILLARY  
LYMPHADENOPATHY, LEFT  
AXILLA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

393 of 2030



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

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



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:27

---

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

Yes ☒

No ☐

---

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

---



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:27

Name of Medication	EFFEXOR XR
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HOT FLASHES
Dose per administration	37.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:27

	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 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:27

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SUPPLEMENTS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:27

	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 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:27

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input 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 checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:27

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		07 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)		15 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:27

Name of Medication	THERAFLU (ACETOMINOPHEN, DEXTROMETHORPHAN,PHENY LEPHRINE HCL)
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SYMPTOMATIC COVID-19
Dose per administration	1
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	TEA BAG
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 checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:27

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3322061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:59:27

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.



US3322061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:27

Date of dosing discontinuation (dd MMM yyyy)

16 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 \_\_\_\_\_



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:27

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 ☐



US3322061

Folder: SAE USA-US060-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:27

SAEID	USA-US060-2020-MRNA-1273-P301000002
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)	2



US3322061

Folder: SAE USA-US060-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:27

SAEID	USA-US060-2020-MRNA-1273-P301000002
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)	2
Date of submission (Pre-filled from custom function)	17/SEP/2020 11:55
<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>	<input checked="" type="checkbox"/> True



US3322061

Folder: SAE USA-US060-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:27

SAEID	USA-US060-2020-MRNA-1273-P301000002
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)	2
Date of submission (Pre-filled from custom function)	23/SEP/2020 14:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3322061 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)



**US3322061**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 10:59:27**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3322061'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 21:59:17



US3322061

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:47:47




US3322061

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	21 Aug 2020 18:47:35
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	21 Aug 2020 16:53:26
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 21:59:18



US3322061

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

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 Aug 2020 18:47:47



**US3322061**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:27**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Aug 2020 18:47:47



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 21:59:19



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

[Age](#)

Audit	User	Time (GMT)
User entered '57'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:27**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Aug 2020 18:48:11



**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:27**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '57'	System	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

White

Audit	User	Time (GMT)
User entered '1'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:27**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:27

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:27**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 10:59:27**

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020' reason for change: New Information	Elisa Moralez (b) (4)	21 Aug 2020 18:47:35
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 16:53:26



**US3322061**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	21 Aug 2020 16:53:26



**US3322061**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 21:59:18



**US3322061**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 10:59:27**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 16:53:35



US3322061

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:59:27

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:53:35



US3322061

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:32



US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:50:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:50:28
Data point term sent to Coder	System	21 Aug 2020 18:49:20
User entered 'Migraine'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:47
	(b) (4)	



US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 1994'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:47



US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1994'	System	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:48:47



US3322061

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:27

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:40:17
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:00:36
User closed query 'Per DM CLR: Please specify the laterality of KNEE ARTHROSCOPY (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:23:40
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:11:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:11:54
Data point term sent to Coder	System	29 Sep 2020 14:10:55
Query 'Per DM CLR: Please specify the laterality of KNEE ARTHROSCOPY (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done, thank you' (Site from DM).	Elisa Moralez (b) (4)	29 Sep 2020 14:10:32
Coding entries removed.	Elisa Moralez (b) (4)	29 Sep 2020 14:10:20
User entered 'Left KNEE ARTHROSCOPY' reason for change: New Information	Elisa Moralez (b) (4)	29 Sep 2020 14:10:20
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 09:22:14



US3322061

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:04:17
User opened query 'Per DM CLR: Please specify the laterality of KNEE ARTHROSCOPY (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:03:29
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Knee arthroscopy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:50:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:50:28
Data point term sent to Coder	System	21 Aug 2020 18:49:21
User entered 'Knee Arthroscopy'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:06



US3322061

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 1992'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:06



US3322061

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:06



US3322061

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:06



US3322061

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 1992'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:06



**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:06



**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	21 Aug 2020 18:49:06



**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1992'	System	21 Aug 2020 18:49:06



**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	21 Aug 2020 18:49:06



**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1992'	System	21 Aug 2020 18:49:06



US3322061

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:51:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:51:29
Data point term sent to Coder	System	21 Aug 2020 18:50:23
User entered 'Cesarean Section'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:25
	(b) (4)	



US3322061

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 1999'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:25



US3322061

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 1999'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1999'	System	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1999'	System	21 Aug 2020 18:49:25



US3322061

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:51:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:51:29
Data point term sent to Coder	System	21 Aug 2020 18:50:23
User entered 'Cesarean Section'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:40
	(b) (4)	



US3322061

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2001'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:40



US3322061

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:40



US3322061

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:40



**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2001'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:40



US3322061

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:49:40



**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	21 Aug 2020 18:49:40



**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2001'	System	21 Aug 2020 18:49:40



**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	21 Aug 2020 18:49:40



**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2001'	System	21 Aug 2020 18:49:40



US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:27

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 18:24:30
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'when there is more than 1 reason a patient is not of childbearing potential, it generates unanswerable queries. Therefore, we entered what is in source for this subject under the childbearing potential page.' (Site from DM).	Elisa Moralez (b) (4)	28 Sep 2020 16:10:45
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:05:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:18:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:18:40
Data point term sent to Coder	System	22 Sep 2020 16:17:23
Coding entries removed.	Frances Saubon (b) (4)	22 Sep 2020 16:16:31
User entered 'BILATERAL TUBAL LIGATION' reason for change: Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 16:16:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:51:29



US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Aug 2020 18:51:29
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 18:50:23
User entered 'Tubal Ligation'	Elisa Morales (b) (4)	21 Aug 2020 18:50:00
	(b) (4)	



US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2001'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:00



US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:00



**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:00



**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2001'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:00



US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:00



**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	21 Aug 2020 18:50:00



**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2001'	System	21 Aug 2020 18:50:00



**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	21 Aug 2020 18:50:00



**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2001'	System	21 Aug 2020 18:50:00



US3322061

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:52:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:52:17
Data point term sent to Coder	System	21 Aug 2020 18:51:25
User entered 'Breast Augmentation'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:34
	(b) (4)	



US3322061

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:34



US3322061

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:34



US3322061

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:34



**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:34



US3322061

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:34



**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Aug 2020 18:50:34



**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Aug 2020 18:50:34



**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	21 Aug 2020 18:50:34



**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2010'	System	21 Aug 2020 18:50:34



US3322061

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:52:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:52:17
Data point term sent to Coder	System	21 Aug 2020 18:51:28
User entered 'Breast Augmentation'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:51
	(b) (4)	



US3322061

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:51



US3322061

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:51



US3322061

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:51



**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:51



**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:50:51



**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	21 Aug 2020 18:50:51



**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2004'	System	21 Aug 2020 18:50:51



**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	21 Aug 2020 18:50:51



**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2004'	System	21 Aug 2020 18:50:51



US3322061

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:27

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: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:52:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:52:17
Data point term sent to Coder	System	21 Aug 2020 18:51:28
User entered 'Penicillin allergy'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:06
	(b) (4)	



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1967'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:06



US3322061

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:06



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:06



US3322061

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:06



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:06



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1967'	System	21 Aug 2020 18:51:06



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1967'	System	21 Aug 2020 18:51:06



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:06



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:06



US3322061

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:27

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Topical adhesive allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 08:01:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 08:01:10
Data point term sent to Coder	System	21 Aug 2020 18:51:28
User entered 'Band-aids allergy'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN UNK 2001'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:19



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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2001'	System	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2001'	System	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:19



US3322061

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:59:27

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: Food allergy, LLT: Shellfish allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:53:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 18:53:19
Data point term sent to Coder	System	21 Aug 2020 18:52:30
User entered 'Shellfish allergy'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:30



**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:30



**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:30



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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:30



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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:30



**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:30



**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	21 Aug 2020 18:51:30



**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1990'	System	21 Aug 2020 18:51:30



**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:30



**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:30



US3322061

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:53:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 18:53:20
Data point term sent to Coder	System	21 Aug 2020 18:52:30
User entered 'Hot Flashes'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:45



US3322061

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:45



US3322061

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:45



US3322061

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:45



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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:45



US3322061

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:59:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:51:45



**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	21 Aug 2020 18:51:45



**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2008'	System	21 Aug 2020 18:51:45



**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:45



**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:51:45



US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:18:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:18:40
Data point term sent to Coder	System	22 Sep 2020 16:17:23
User entered 'Post-menopausal'	Frances Saubon (b) (4)	22 Sep 2020 16:17:06
	(b) (4)	



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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 16:17:06



US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:59:27

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 16:17:06



US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 16:17:06



US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 16:17:06



US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:59:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 16:17:06



**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	22 Sep 2020 16:17:06



**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2008'	System	22 Sep 2020 16:17:06



**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 16:17:06



**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 16:17:06



US3322061

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 16:36:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 16:36:45
Data point term sent to Coder	System	29 Oct 2020 16:35:21
User entered 'Left Knee Torn Meniscus'	Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43



US3322061

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 1992'	Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:59:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43



US3322061

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 1992'	Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:59:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1992'	System	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '1992'	System	29 Oct 2020 16:34:43



US3322061

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:59:27

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Abdominal therapeutic procedures NEC, PT: Abdominoplasty, LLT: Abdominoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:48:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:48:43
Data point term sent to Coder	System	29 Oct 2020 18:47:58
User entered 'Abdominoplasty'	Frances Saubon (b) (4)	29 Oct 2020 18:47:12
	(b) (4)	



US3322061

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Frances Saubon (b) (4) (b) (4)	29 Oct 2020 18:47:12



**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	29 Oct 2020 18:47:12



US3322061

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:59:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	29 Oct 2020 18:47:12



US3322061

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Frances Saubon (b) (4) (b) (4)	29 Oct 2020 18:47:12



US3322061

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 10:59:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	29 Oct 2020 18:47:12



**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	29 Oct 2020 18:47:12



**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2004'	System	29 Oct 2020 18:47:12



**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	29 Oct 2020 18:47:12



**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '2004'	System	29 Oct 2020 18:47:12



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 08:10:23
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'SPLIT VISIT- PER SOURCE' (Site from System).	Elisa Moralez (b) (4)	21 Aug 2020 18:52:38
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	21 Aug 2020 18:52:25
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider changing 8:48 to 08:48 because time format is 24HR. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 10:38:58
Query 'Per CDM: Please consider changing 8:48 to 08:48 because time format is 24HR. Thank you!' answered with 'TIME UPDATED PER QUERY' (Site from DM).	Blessing Felix-Okoroji (b) (4)	01 Oct 2020 13:33:10
User entered '08:48' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	01 Oct 2020 13:32:57
User opened query 'Per CDM: Please consider changing 8:48 to 08:48 because time format is 24HR. Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:26:11
User closed query 'Per CDM: Please confirm if time 8:48 is AM or PM. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:59:23
Query 'Per CDM: Please confirm if time 8:48 is AM or PM. Thank you' answered with '8:48 AM' (Site from DM).	Blessing Felix-Okoroji (b) (4)	24 Sep 2020 20:04:47
User opened query 'Per CDM: Please confirm if time 8:48 is AM or PM. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:14:09
User entered '8:48'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



**US3322061**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 08:48'	System	01 Oct 2020 13:32:57
User entered '21 Aug 2020 8:48'	System	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '66' in	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25
DataPoint set to visible.	(b) (4) System	21 Aug 2020 16:53:35



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '154.4' lb	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25
DataPoint set to visible.	(b) (4) System	21 Aug 2020 16:53:35



**US3322061**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
Amendment Manager: User entered '24.97292'	System	17 Sep 2020 00:17:22
User entered '25.0'	System	21 Aug 2020 18:52:25
DataPoint set to visible.	System	21 Aug 2020 16:53:35



**US3322061**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	21 Aug 2020 18:52:25
DataPoint set to visible.	System	21 Aug 2020 16:53:35



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[If Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	21 Aug 2020 18:52:56
User entered missing code ND - Not Done; reason for change New Information	Elisa Moralez (b) (4)	21 Aug 2020 18:52:56
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	21 Aug 2020 18:52:25
	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25
	(b) (4)	



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



**US3322061**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



**US3322061**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:07



US3322061

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:07



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	21 Aug 2020 18:53:59
User entered '20 Aug 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	21 Aug 2020 18:53:59
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	21 Aug 2020 18:53:28
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

If No, what is the reason?

Audit	User	Time (GMT)
Comment added 'Data updated'.	Frances Saubon (b) (4)	22 Sep 2020 16:17:38
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:28:39
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'Noted, data will be updated once source is updated, thank you.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 14:07:40
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 06:06:28
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:27

Date of last menstruation unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**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)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**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)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**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)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**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)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**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)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

[Specify](#)

Audit	User	Time (GMT)
User entered (b) (6)	Elisa Moralez (b) (4)	21 Aug 2020 18:54:56
(b) (6)	(b) (4)	
RETIRED, BUT SEES 10-25 PATIENTS ONE DAY PER WEEK		

AROUND 40 PEOPLE AT A TIME FOR WORK

ABOUT 2X PER MONTH TRAVELS,' reason for change: Per Query Resolution

User entered (b) (6)	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44
(b) (6) retired, but sees 10-25 patients one day per week	(b) (4)	

around 40 people at a time for work

about 2x per month travels, may stay over a weekend to continue working 2x per week' (non-conformant).



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

**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'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '1'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:27

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:54:44



US3322061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation Re-query: Swab: Please enter data in Covid-19 Assessment Folder.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:06:00
Query 'Per GCL Lab Reconciliation Re-query: Swab: Frances Saubon Please enter data in Covid-19 Assessment Folder.' answered with 'Site has added a new Covid-19 Assessment Folder to reflect the data for swab sample dated on 14-Oct-2020. Please advise if this step is sufficient to reflect correct data or if site needs to replace the initial value results for the first Covid-19 Assessment Folder dated on the 11-Sep-2020 as these instructions are not in the eCRF guidelines. Thank you.' (Site from DM).	(b) (4) (b) (4)	19 Nov 2020 16:18:42
User opened query 'Per GCL Lab Reconciliation Re-query: Swab: Please enter data in Covid-19 Assessment Folder.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:46:11
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 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)	19 Nov 2020 12:46:11
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 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 'Noted, a DCF will be submitted to reflect correct information. Nasal swab collected on 14-Oct-2020 for Convalescent D28 however, there is no form under Convalescent Visit Day 28 folder to report Nasal Swab. Please advise on how we are to report this data or if we are to change the data under COVID-19 Assessment folder Nasal swab results. Thank you.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	02 Nov 2020 15:55:58



US3322061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14OCT2020 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 06:12:05
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:55:11



US3322061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:55:11



US3322061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

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 Aug 2020 18:55:11



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:27**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Aug 2020 18:55:11



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	21 Aug 2020 15:39:25



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '106726'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	21 Aug 2020 15:39:25



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Aug 2020 15:39:25



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

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)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:55:23



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:55:23



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:55:23



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:55:23



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:55:23



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 19:23:59
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:37:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:53:31



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:27

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:27

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:27

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:27

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '8:48'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 8:48'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.0' F	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

Pulse (xxx)

Audit	User	Time (GMT)
User entered '66'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '15'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:27

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:27

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '12:15'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:15'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

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 06:15:18
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.'	(b) (4), (b) (6)	17 Sep 2020 18:49:19
answered with 'NCS' (Site from System).		
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	17 Sep 2020 00:17:22
User entered '96.5' F	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

Pulse (xxx)

Audit	User	Time (GMT)
User entered '62'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '15'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '141'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:05



US3322061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

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)	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:42'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:54:05



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 10:59:27**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:42'	System	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:27

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:19



US3322061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:19



US3322061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:30'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:19



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 10:59:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:30'	System	21 Aug 2020 18:57:19



US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:28



US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:27

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:28



US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:28



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '11:26'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:28



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:26'	System	21 Aug 2020 18:57:28



US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:27

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:28



US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:28



US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:28



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 18:57:28



US3322061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:57:33



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 18:57:33



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:14:55', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '451ac73b-2915-44fe-926a-6cec104bc3f6'	System	21 Aug 2020 17:15:40
User entered 'Yes (Y)'	System	21 Aug 2020 17:15:40



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:01', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '451ac73b-2915-44fe-926a-6cec104bc3f6'	System	21 Aug 2020 17:15:40
User entered '96.5'	System	21 Aug 2020 17:15:40



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:10', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '451ac73b-2915-44fe-926a-6cec104bc3f6'	System	21 Aug 2020 17:15:40
User entered 'No (N)'	System	21 Aug 2020 17:15:40



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:17', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '451ac73b-2915-44fe-926a-6cec104bc3f6'	System	21 Aug 2020 17:15:40
User entered '21 Aug 2020 12:15'	System	21 Aug 2020 17:15:40



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:02'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 14:32'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:28:46', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '8895544c-ba1f-4999-9000-149bcc0dccc5'	System	22 Aug 2020 03:29:07
User entered 'Yes (Y)'	System	22 Aug 2020 03:29:07



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:28:54', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '8895544c-ba1f-4999-9000-149bcc0dccc5'	System	22 Aug 2020 03:29:07
User entered '97.0'	System	22 Aug 2020 03:29:07



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:28:57', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '8895544c-ba1f-4999-9000-149bcc0dccc5'	System	22 Aug 2020 03:29:07
User entered 'No (N)'	System	22 Aug 2020 03:29:07



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:01', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '8895544c-ba1f-4999-9000-149bcc0dccc5'	System	22 Aug 2020 03:29:07
User entered '21 Aug 2020 22:29'	System	22 Aug 2020 03:29:07



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 15:27'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 2'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:40:22', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5dfd565d-e965-413c-8c4b-6d5f437c1a6f'	System	23 Aug 2020 04:41:07
User entered 'Yes (Y)'	System	23 Aug 2020 04:41:07



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:40:58', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5dfd565d-e965-413c-8c4b-6d5f437c1a6f'	System	23 Aug 2020 04:41:07
User entered '97.5'	System	23 Aug 2020 04:41:07



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:02', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5dfd565d-e965-413c-8c4b-6d5f437c1a6f'	System	23 Aug 2020 04:41:07
User entered 'No (N)'	System	23 Aug 2020 04:41:07



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:06', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5dfd565d-e965-413c-8c4b-6d5f437c1a6f'	System	23 Aug 2020 04:41:07
User entered '22 Aug 2020 23:41'	System	23 Aug 2020 04:41:07



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 3'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:12', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '60ad83d1-c7c8-45ac-bec5-b24d61f485d5'	System	24 Aug 2020 00:44:24
User entered 'Yes (Y)'	System	24 Aug 2020 00:44:24



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:16', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '60ad83d1-c7c8-45ac-bec5-b24d61f485d5'	System	24 Aug 2020 00:44:24
User entered '97.8'	System	24 Aug 2020 00:44:24



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:18', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '60ad83d1-c7c8-45ac-bec5-b24d61f485d5'	System	24 Aug 2020 00:44:24
User entered 'No (N)'	System	24 Aug 2020 00:44:24



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:21', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '60ad83d1-c7c8-45ac-bec5-b24d61f485d5'	System	24 Aug 2020 00:44:24
User entered '23 Aug 2020 19:44'	System	24 Aug 2020 00:44:24



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 26 Nov 2020 10:59:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 4'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:02', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'cbe65d24-43a4-4671-9b4e-023c3dc272e6'	System	24 Aug 2020 22:53:13
User entered 'Yes (Y)'	System	24 Aug 2020 22:53:13



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:06', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'cbe65d24-43a4-4671-9b4e-023c3dc272e6'	System	24 Aug 2020 22:53:13
User entered '96.6'	System	24 Aug 2020 22:53:13



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:09', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'cbe65d24-43a4-4671-9b4e-023c3dc272e6'	System	24 Aug 2020 22:53:13
User entered 'No (N)'	System	24 Aug 2020 22:53:13



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:12', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'cbe65d24-43a4-4671-9b4e-023c3dc272e6'	System	24 Aug 2020 22:53:13
User entered '24 Aug 2020 18:53'	System	24 Aug 2020 22:53:13



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 5'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:13:42', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '37450a13-a7ed-4a46-88e8-fb7a9a8dbc1c'	System	25 Aug 2020 22:14:00
User entered 'Yes (Y)'	System	25 Aug 2020 22:14:00



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:13:48', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '37450a13-a7ed-4a46-88e8-fb7a9a8dbc1c' User entered '97.2'	System	25 Aug 2020 22:14:00
	System	25 Aug 2020 22:14:00



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:13:50', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '37450a13-a7ed-4a46-88e8-fb7a9a8dbc1c'	System	25 Aug 2020 22:14:00
User entered 'No (N)'	System	25 Aug 2020 22:14:00



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:13:55', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '37450a13-a7ed-4a46-88e8-fb7a9a8dbc1c'	System	25 Aug 2020 22:14:00
User entered '25 Aug 2020 18:13'	System	25 Aug 2020 22:14:00



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 6'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:12', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'a604c0ab-7525-49b3-941f-e267eff7d476'	System	27 Aug 2020 01:13:24
User entered 'Yes (Y)'	System	27 Aug 2020 01:13:24



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:18', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'a604c0ab-7525-49b3-941f-e267eff7d476'	System	27 Aug 2020 01:13:24
User entered '97.6'	System	27 Aug 2020 01:13:24



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:20', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'a604c0ab-7525-49b3-941f-e267eff7d476'	System	27 Aug 2020 01:13:24
User entered 'No (N)'	System	27 Aug 2020 01:13:24



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:22', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'a604c0ab-7525-49b3-941f-e267eff7d476'	System	27 Aug 2020 01:13:24
User entered '26 Aug 2020 21:13'	System	27 Aug 2020 01:13:24



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 7'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:21', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '283f1b1a-0d51-4995-a95c-c3cc637a9aa1'	System	28 Aug 2020 01:53:19
User entered 'Yes (Y)'	System	28 Aug 2020 01:53:19



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:53:06', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '283f1b1a-0d51-4995-a95c-c3cc637a9aa1'	System	28 Aug 2020 01:53:19
User entered '97.6'	System	28 Aug 2020 01:53:19



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:53:09', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '283f1b1a-0d51-4995-a95c-c3cc637a9aa1'	System	28 Aug 2020 01:53:19
User entered 'No (N)'	System	28 Aug 2020 01:53:19



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:53:13', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '283f1b1a-0d51-4995-a95c-c3cc637a9aa1'	System	28 Aug 2020 01:53:19
User entered '27 Aug 2020 20:53'	System	28 Aug 2020 01:53:19



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:24', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7baef1d7-0201-4a07-823c-992d66b5b6b6'	System	21 Aug 2020 17:15:49
User entered 'None (1)'	System	21 Aug 2020 17:15:49



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:27', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7baef1d7-0201-4a07-823c-992d66b5b6b6'	System	21 Aug 2020 17:15:49
User entered 'No (N)'	System	21 Aug 2020 17:15:49



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:29', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7baef1d7-0201-4a07-823c-992d66b5b6b6'	System	21 Aug 2020 17:15:49
User entered 'No (N)'	System	21 Aug 2020 17:15:49



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:37', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7baef1d7-0201-4a07-823c-992d66b5b6b6'	System	21 Aug 2020 17:15:49
User entered 'None (1)'	System	21 Aug 2020 17:15:49



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:47', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7baef1d7-0201-4a07-823c-992d66b5b6b6'	System	21 Aug 2020 17:15:49
User entered '21 Aug 2020 12:15'	System	21 Aug 2020 17:15:49



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:02'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 14:32'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:10', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c1786bfe-c4e2-408b-8365-4097e4d72f17'	System	22 Aug 2020 03:29:23
User entered 'None (1)'	System	22 Aug 2020 03:29:23



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:12', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c1786bfe-c4e2-408b-8365-4097e4d72f17'	System	22 Aug 2020 03:29:23
User entered 'No (N)'	System	22 Aug 2020 03:29:23



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:14', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c1786bfe-c4e2-408b-8365-4097e4d72f17'	System	22 Aug 2020 03:29:23
User entered 'No (N)'	System	22 Aug 2020 03:29:23



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:17', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c1786bfe-c4e2-408b-8365-4097e4d72f17'	System	22 Aug 2020 03:29:23
User entered 'None (1)'	System	22 Aug 2020 03:29:23



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:20', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c1786bfe-c4e2-408b-8365-4097e4d72f17'	System	22 Aug 2020 03:29:23
User entered '21 Aug 2020 22:29'	System	22 Aug 2020 03:29:23



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 15:27'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 2'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:10', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0945e345-96fb-448e-8591-3fce50b71450'	System	23 Aug 2020 04:41:34
User entered 'None (1)'	System	23 Aug 2020 04:41:34



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:14', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0945e345-96fb-448e-8591-3fce50b71450'	System	23 Aug 2020 04:41:34
User entered 'No (N)'	System	23 Aug 2020 04:41:34



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:17', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0945e345-96fb-448e-8591-3fce50b71450'	System	23 Aug 2020 04:41:34
User entered 'No (N)'	System	23 Aug 2020 04:41:34



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:25', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0945e345-96fb-448e-8591-3fce50b71450'	System	23 Aug 2020 04:41:34
User entered 'None (1)'	System	23 Aug 2020 04:41:34



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:28', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0945e345-96fb-448e-8591-3fce50b71450'	System	23 Aug 2020 04:41:34
User entered '22 Aug 2020 23:41'	System	23 Aug 2020 04:41:34



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 3'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:24', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '2829c2d8-880f-4658-b1fb-0e7cef4b7025'	System	24 Aug 2020 00:44:36
User entered 'None (1)'	System	24 Aug 2020 00:44:36



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:27', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '2829c2d8-880f-4658-b1fb-0e7cef4b7025'	System	24 Aug 2020 00:44:36
User entered 'No (N)'	System	24 Aug 2020 00:44:36



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:29', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '2829c2d8-880f-4658-b1fb-0e7cef4b7025'	System	24 Aug 2020 00:44:36
User entered 'No (N)'	System	24 Aug 2020 00:44:36



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:31', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '2829c2d8-880f-4658-b1fb-0e7cef4b7025'	System	24 Aug 2020 00:44:36
User entered 'None (1)'	System	24 Aug 2020 00:44:36



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:33', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '2829c2d8-880f-4658-b1fb-0e7cef4b7025'	System	24 Aug 2020 00:44:36
User entered '23 Aug 2020 19:44'	System	24 Aug 2020 00:44:36



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 4'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:15', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '924f2f32-7f5a-4695-bced-0cb169e598ec'	System	24 Aug 2020 22:53:24
User entered 'None (1)'	System	24 Aug 2020 22:53:24



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:17', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '924f2f32-7f5a-4695-bced-0cb169e598ec'	System	24 Aug 2020 22:53:24
User entered 'No (N)'	System	24 Aug 2020 22:53:24



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:19', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '924f2f32-7f5a-4695-bced-0cb169e598ec'	System	24 Aug 2020 22:53:24
User entered 'No (N)'	System	24 Aug 2020 22:53:24



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:21', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '924f2f32-7f5a-4695-bced-0cb169e598ec'	System	24 Aug 2020 22:53:24
User entered 'None (1)'	System	24 Aug 2020 22:53:24



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:23', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '924f2f32-7f5a-4695-bced-0cb169e598ec'	System	24 Aug 2020 22:53:24
User entered '24 Aug 2020 18:53'	System	24 Aug 2020 22:53:24



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 5'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:13:59', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9d295b7a-7690-403e-bc87-fdc55586d306'	System	25 Aug 2020 22:14:08
User entered 'None (1)'	System	25 Aug 2020 22:14:08



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:02', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9d295b7a-7690-403e-bc87-fdc55586d306'	System	25 Aug 2020 22:14:08
User entered 'No (N)'	System	25 Aug 2020 22:14:08



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:03', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9d295b7a-7690-403e-bc87-fdc55586d306'	System	25 Aug 2020 22:14:08
User entered 'No (N)'	System	25 Aug 2020 22:14:08



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:04', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9d295b7a-7690-403e-bc87-fdc55586d306'	System	25 Aug 2020 22:14:08
User entered 'None (1)'	System	25 Aug 2020 22:14:08



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:06', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9d295b7a-7690-403e-bc87-fdc55586d306'	System	25 Aug 2020 22:14:08
User entered '25 Aug 2020 18:14'	System	25 Aug 2020 22:14:08



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 6'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:26', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '694eccbc-5756-46e8-96e6-5482bbd941f0'	System	27 Aug 2020 01:13:40
User entered 'None (1)'	System	27 Aug 2020 01:13:40



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:28', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '694eccbc-5756-46e8-96e6-5482bbd941f0'	System	27 Aug 2020 01:13:40
User entered 'No (N)'	System	27 Aug 2020 01:13:40



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:29', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '694eccbc-5756-46e8-96e6-5482bbd941f0'	System	27 Aug 2020 01:13:40
User entered 'No (N)'	System	27 Aug 2020 01:13:40



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:35', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '694eccbc-5756-46e8-96e6-5482bbd941f0'	System	27 Aug 2020 01:13:40
User entered 'None (1)'	System	27 Aug 2020 01:13:40



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:38', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '694eccbc-5756-46e8-96e6-5482bbd941f0'	System	27 Aug 2020 01:13:40
User entered '26 Aug 2020 21:13'	System	27 Aug 2020 01:13:40



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 7'	System	21 Aug 2020 16:54:05



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:51:47', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3462ee65-3fb5-478d-aeb3-1c06cc46f23a'	System	28 Aug 2020 01:52:04
User entered 'None (1)'	System	28 Aug 2020 01:52:04



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:51:50', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3462ee65-3fb5-478d-aeb3-1c06cc46f23a'	System	28 Aug 2020 01:52:04
User entered 'No (N)'	System	28 Aug 2020 01:52:04



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:51:52', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3462ee65-3fb5-478d-aeb3-1c06cc46f23a'	System	28 Aug 2020 01:52:04
User entered 'No (N)'	System	28 Aug 2020 01:52:04



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:51:57', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3462ee65-3fb5-478d-aeb3-1c06cc46f23a'	System	28 Aug 2020 01:52:04
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3462ee65-3fb5-478d-aeb3-1c06cc46f23a'	System	28 Aug 2020 01:52:04
User entered '27 Aug 2020 20:52'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:52', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered 'None (0)'	System	21 Aug 2020 17:16:09



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:54', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered 'None (0)'	System	21 Aug 2020 17:16:09



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:56', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered 'None (0)'	System	21 Aug 2020 17:16:09



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:58', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered 'None (0)'	System	21 Aug 2020 17:16:09



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:15:59', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered 'None (0)'	System	21 Aug 2020 17:16:09



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:16:01', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered 'None (0)'	System	21 Aug 2020 17:16:09



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:16:05', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered 'No (N)'	System	21 Aug 2020 17:16:09



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T12:16:08', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0d388dea-7868-41b5-837a-dfaf97dca044'	System	21 Aug 2020 17:16:09
User entered '21 Aug 2020 12:16'	System	21 Aug 2020 17:16:09



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:02'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 14:32'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:24', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered 'None (0)'	System	22 Aug 2020 03:29:38



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:25', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered 'None (0)'	System	22 Aug 2020 03:29:38



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:26', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered 'None (0)'	System	22 Aug 2020 03:29:38



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:28', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered 'None (0)'	System	22 Aug 2020 03:29:38



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:29', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered 'None (0)'	System	22 Aug 2020 03:29:38



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:30', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered 'None (0)'	System	22 Aug 2020 03:29:38



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:33', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered 'No (N)'	System	22 Aug 2020 03:29:38



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-21T22:29:36', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9301d73b-0529-4d38-81a6-e6457b5335e1'	System	22 Aug 2020 03:29:38
User entered '21 Aug 2020 22:29'	System	22 Aug 2020 03:29:38



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 15:27'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 2'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:34', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered 'None (0)'	System	23 Aug 2020 04:41:47



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:35', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered 'None (0)'	System	23 Aug 2020 04:41:47



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:37', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered 'None (0)'	System	23 Aug 2020 04:41:47



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:38', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered 'None (0)'	System	23 Aug 2020 04:41:47



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:40', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered 'None (0)'	System	23 Aug 2020 04:41:47



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:41', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered 'None (0)'	System	23 Aug 2020 04:41:47



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:43', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered 'No (N)'	System	23 Aug 2020 04:41:47



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-22T23:41:46', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1e500306-a8c6-4aaf-b96d-e726df9dac3d'	System	23 Aug 2020 04:41:47
User entered '22 Aug 2020 23:41'	System	23 Aug 2020 04:41:47



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 3'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:36', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered 'None (0)'	System	24 Aug 2020 00:44:53



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:38', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered 'None (0)'	System	24 Aug 2020 00:44:53



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:40', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered 'None (0)'	System	24 Aug 2020 00:44:53



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:41', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered 'None (0)'	System	24 Aug 2020 00:44:53



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:42', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered 'None (0)'	System	24 Aug 2020 00:44:53



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:44', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered 'None (0)'	System	24 Aug 2020 00:44:53



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:47', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered 'No (N)'	System	24 Aug 2020 00:44:53



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-23T19:44:49', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'c71d437e-b68f-4c56-823a-bfbb95a63c17'	System	24 Aug 2020 00:44:53
User entered '23 Aug 2020 19:44'	System	24 Aug 2020 00:44:53



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 4'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:26', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered 'None (0)'	System	24 Aug 2020 22:53:39



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:28', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered 'None (0)'	System	24 Aug 2020 22:53:39



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:29', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered 'None (0)'	System	24 Aug 2020 22:53:39



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:31', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered 'None (0)'	System	24 Aug 2020 22:53:39



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:32', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered 'None (0)'	System	24 Aug 2020 22:53:39



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:33', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered 'None (0)'	System	24 Aug 2020 22:53:39



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:36', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered 'No (N)'	System	24 Aug 2020 22:53:39



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-24T18:53:37', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '1c55e199-c630-493c-b501-982bfec608a3'	System	24 Aug 2020 22:53:39
User entered '24 Aug 2020 18:53'	System	24 Aug 2020 22:53:39



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 5'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:09', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered 'None (0)'	System	25 Aug 2020 22:14:22



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:11', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered 'None (0)'	System	25 Aug 2020 22:14:22



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:12', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered 'None (0)'	System	25 Aug 2020 22:14:22



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:13', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered 'None (0)'	System	25 Aug 2020 22:14:22



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:14', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered 'None (0)'	System	25 Aug 2020 22:14:22



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:15', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered 'None (0)'	System	25 Aug 2020 22:14:22



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:17', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered 'No (N)'	System	25 Aug 2020 22:14:22



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-25T18:14:19', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7bdcc1d0-a98c-4652-8f0b-cc37fa82768e'	System	25 Aug 2020 22:14:22
User entered '25 Aug 2020 18:14'	System	25 Aug 2020 22:14:22



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 10:59:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 6'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:41', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered 'None (0)'	System	27 Aug 2020 01:13:57



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:43', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered 'None (0)'	System	27 Aug 2020 01:13:57



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:44', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered 'None (0)'	System	27 Aug 2020 01:13:57



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:45', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered 'None (0)'	System	27 Aug 2020 01:13:57



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:46', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered 'None (0)'	System	27 Aug 2020 01:13:57



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:47', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered 'None (0)'	System	27 Aug 2020 01:13:57



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:50', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered 'No (N)'	System	27 Aug 2020 01:13:57



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-26T21:13:53', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f93d611-cbd4-4f08-8e99-2d91429e06b0'	System	27 Aug 2020 01:13:57
User entered '26 Aug 2020 21:13'	System	27 Aug 2020 01:13:57



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 7'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:03', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered 'None (0)'	System	28 Aug 2020 01:52:16



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:05', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered 'None (0)'	System	28 Aug 2020 01:52:16



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:06', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered 'None (0)'	System	28 Aug 2020 01:52:16



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:07', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered 'None (0)'	System	28 Aug 2020 01:52:16



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:09', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered 'None (0)'	System	28 Aug 2020 01:52:16



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

**CHILLS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:10', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered 'None (0)'	System	28 Aug 2020 01:52:16



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:13', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered 'No (N)'	System	28 Aug 2020 01:52:16



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-27T20:52:14', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '3f79477f-f451-4f91-b88a-fb6fd7c05051'	System	28 Aug 2020 01:52:16
User entered '27 Aug 2020 20:52'	System	28 Aug 2020 01:52:16



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:54:05



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:52:04
User entered 'Day 9'	System	28 Aug 2020 01:52:04



US3322061

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-29T20:28:59', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9b9e579f-2715-4394-beb8-8584ad0e6294'	System	30 Aug 2020 01:29:06
User entered 'No (N)'	System	30 Aug 2020 01:29:06



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-29T20:29:02', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9b9e579f-2715-4394-beb8-8584ad0e6294'	System	30 Aug 2020 01:29:06
User entered '29 Aug 2020 20:29'	System	30 Aug 2020 01:29:06



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:52:04
User entered 'Day 8'	System	28 Aug 2020 01:52:04



US3322061

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(8)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-28T20:26:46', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'aa026442-7255-47ed-901b-0a4059c35e27'	System	29 Aug 2020 01:26:50
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 01:26:50



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-28T20:26:49', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'aa026442-7255-47ed-901b-0a4059c35e27'	System	29 Aug 2020 01:26:50
User entered '28 Aug 2020 20:26'	System	29 Aug 2020 01:26:50



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 01:52:04
User entered 'Day 9'	System	28 Aug 2020 01:52:04



US3322061

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 26 Nov 2020 10:59:27

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 (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-29T20:29:16', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f52bc57-204c-49e1-8c59-bcd0591f33f9'	System	30 Aug 2020 01:29:21
User entered 'None (1)'	System	30 Aug 2020 01:29:21



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (90BA33E2-64E2-4B7E-89DA-3CE82FBA31C5)', Time: '2020-08-29T20:29:18', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '5f52bc57-204c-49e1-8c59-bcd0591f33f9'	System	30 Aug 2020 01:29:21
User entered '29 Aug 2020 20:29'	System	30 Aug 2020 01:29:21



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Open Date and Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(9)**

**Generated On: 26 Nov 2020 10:59:27**

[PC Close Date and Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 01:52:04



**US3322061**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:17:09



US3322061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 14:21:23
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'this is when final contact was attempted' (Site from System).	Elisa Moralez (b) (4)	10 Nov 2020 14:31:24
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Nov 2020 14:30:40
User entered '03 Sep 2020' reason for change: Per Query Resolution	Elisa Moralez (b) (4)	10 Nov 2020 14:30:40
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 11:38:30
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'per source, this was the last day contact was made' (Site from System).	Elisa Moralez (b) (4)	09 Sep 2020 13:18:16
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 13:17:09
User entered '3 Sep 2020'	Elisa Moralez (b) (4)	09 Sep 2020 13:17:09



US3322061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:17:09



**US3322061**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:27**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered '3 unsuccessful attempt to contact subject'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:17:09



US3322061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:17:50



**US3322061**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 13:17:50



**US3322061**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:18:24



**US3322061**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: Per Query Resolution	Elisa Moralez (b) (4)	10 Nov 2020 14:31:32
User entered '4 Sep 2020'	Elisa Moralez (b) (4)	09 Sep 2020 13:18:24



US3322061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

[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)	09 Sep 2020 13:18:24



**US3322061**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:27**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:18:24



US3322061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Sep 2020 13:18:28



**US3322061**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 13:18:28



US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:58:50



US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:58:50



US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:27

[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)	11 Sep 2020 20:58:50



**US3322061**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 10:59:27**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:58:50



US3322061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 20:58:54



**US3322061**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 10:59:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 20:58:54



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Oct 2020 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '22 Oct 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Oct 2020 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '29 Oct 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '01 Nov 2020 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '05 Nov 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:17:58



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

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:17:58



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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:17:58



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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:17:58



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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:17:58



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:17:58



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

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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:17:58



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**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:17:58



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

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:17:58



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**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:17:58



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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:17:58



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**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:17:58



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 10:59:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:17:58
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:17:58



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:26:47
User entered '11 Sep 2020'	Frances Saubon (b) (4)	16 Sep 2020 17:51:46
	(b) (4)	



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:26:47
User entered '00:00'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 17:51:46



**US3322061**

**Folder: Covid-19 Assessment 11 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:59:27**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 00:00'	System	16 Sep 2020 17:51:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:26:47
User entered 'Safety Call (Safety Call)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 17:51:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:26:47
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 17:51:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 2 (Day 2)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:24:57
User entered '14 Sep 2020'	Frances Saubon (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:38:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:45:56
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 20:45:56
User entered empty.	System	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Sep 2020 20:38:59
User entered '97.8' F reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:38:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Sep 2020 20:38:54
User entered '97.8' (non-conformant).	Frances Saubon (b) (4)	21 Sep 2020 20:38:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:45:56
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:20:12



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 3 (Day 3)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 15:53:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:46:41
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



**US3322061**

**Folder: Covid-19 Assessment 11 Sep 2020**

**Form: Symptom Log (2)**

**Generated On: 26 Nov 2020 10:59:27**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 20:46:41
User entered empty.	System	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.4' F reason for change: Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 15:53:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:46:41
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:24:57



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 4 (Day 4)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '97' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:42:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:04
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 20:47:04
User entered empty.	System	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.5' F reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:42:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:04
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 5 (Day 5)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:43:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:15
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 20:47:15
User entered empty.	System	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.6' F reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:43:06
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:15
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:01



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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
Data Entry Error	(b) (4)	
User entered 'Day 6 (Day 6)'	Frances Saubon (b) (4)	16 Sep 2020 19:44:48
	(b) (4)	



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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:25
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 20:47:25
User entered empty.	System	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.3' F reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:43:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:25
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:44:48



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change:	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
Data Entry Error	(b) (4)	
User entered 'Day 7 (Day 7)'	Frances Saubon (b) (4)	17 Sep 2020 21:59:01
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:44:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:33
User entered empty.	Frances Saubon (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 20:47:33
User entered empty.	System	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:44:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 20:47:33
User entered empty.	Frances Saubon (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

Date

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm Symptoms registered for 08, 09, 10 and 11 Sep 2020 if available, thanks' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 03:58:02
User closed query 'Per CDM: Please update the sections from symptoms for 08, 09, 10 and 11 Sep 2020, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:15:11
Query 'Per CDM: Please update the sections from symptoms for 08, 09, 10 and 11 Sep 2020, else provide clarification.' answered with 'Symptom assessments were not done on the following dates: 08, 09, 10 and 11 Sep 2020' (Site from DM).	Frances Saubon (b) (4)	28 Oct 2020 13:58:19
User opened query 'Per CDM: Please update the sections from symptoms for 08, 09, 10 and 11 Sep 2020, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:44:24
Query 'Per CDM: Please update the sections for symptoms for 08, 09, 10 and 11 Sep 2020, else provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:44:16
User opened query 'Per CDM: Please update the sections for symptoms for 08, 09, 10 and 11 Sep 2020, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:44:07
Query 'Per ETRTR: Please confirm Symptoms registered for 08, 09, 10 and 11 Sep 2020 if available, thanks' answered with 'DONE' (Site from CRA).	Elisa Moralez (b) (4)	28 Sep 2020 16:11:54
User opened query 'Per ETRTR: Please confirm Symptoms registered for 08, 09, 10 and 11 Sep 2020 if available, thanks' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 00:25:08
User entered '7 Sep 2020'	Elisa Moralez (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:52:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change:	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
Data Entry Error	(b) (4)	
User entered 'Day 8 (Day 8)'	Frances Saubon (b) (4)	18 Sep 2020 20:53:44
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:54:35
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:54:35
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 20:53:44



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change:	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
Data Entry Error	(b) (4)	
User entered 'Day 9 (Day 9)'	Frances Saubon (b) (4)	21 Sep 2020 20:55:53
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.3' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change:	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
Data Entry Error	(b) (4)	
User entered 'Day 10 (Day 10)'	Frances Saubon (b) (4)	21 Sep 2020 20:57:17
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



**US3322061**

**Folder: Covid-19 Assessment 11 Sep 2020**

**Form: Symptom Log (10)**

**Generated On: 26 Nov 2020 10:59:27**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:03:31
User entered 'Day 11 (Day 11)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 15:46:24



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)' reason for change:	Elisa Moralez (b) (4)	29 Sep 2020 16:03:31
Data Entry Error	(b) (4)	
User entered 'Day 12 (Day 12)'	Frances Saubon (b) (4)	23 Sep 2020 22:00:42
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



**US3322061**

**Folder: Covid-19 Assessment 11 Sep 2020**

**Form: Symptom Log (12)**

**Generated On: 26 Nov 2020 10:59:27**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.6' F	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	23 Sep 2020 22:00:42



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)' reason for change:	Elisa Moralez (b) (4)	29 Sep 2020 16:03:31
Data Entry Error	(b) (4)	
User entered 'Day 13 (Day 13)'	Frances Saubon (b) (4)	24 Sep 2020 21:25:46
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



**US3322061**

**Folder: Covid-19 Assessment 11 Sep 2020**

**Form: Symptom Log (13)**

**Generated On: 26 Nov 2020 10:59:27**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.3' F	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:25:46



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	29 Sep 2020 19:05:58
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:04:56
User entered 'Day 14 (Day 14)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.2' F	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 22:58:27



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:05



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:14



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Date](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



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**Folder: Covid-19 Assessment 11 Sep 2020**

**Form: Symptom Log (20)**

**Generated On: 26 Nov 2020 10:59:27**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:01:35



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[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 14OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:27:20
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 14OCT2020. Please reconcile or clarify.' answered with 'please note that on these days, there is nothing listed in progress notes left by those who saw the patient, including the doctor, which indicate which symptoms the patient was feeling that brought them in for their illness visit. This also means that there is no information on the severity of those symptoms from these very old dates. Data entered matches source, as we cannot elaborate on data that is not available' (Site from DM).	Elisa Moralez (b) (4)	09 Nov 2020 16:02:00
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 14OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:24:43
User entered '11 Sep 2020'	Elisa Moralez (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 10:59:27

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 16:02:04



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered '11 Sep 2020'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 20:34:29



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 20:34:29



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
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)	17 Sep 2020 13:39:57
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 'yes confirmed, data has been entered on AE form' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 01:51:30
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	16 Sep 2020 20:34:29
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 20:34:29



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered '11 Sep 2020'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 20:34:29



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

Type of Test Performed

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered 'Nasal Swab (Nasal Swab)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 20:34:29



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 20:34:29
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[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 20:27:21
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 20:34:29



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 20:34:29
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered empty.	Frances Saubon (b) (4)	16 Sep 2020 20:34:29
	(b) (4)	



**US3322061**

**Folder: Covid-19 Assessment 11 Sep 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:59:27**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 20:34:29



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

Did the subject have Oxygen Saturation of  $\text{SpO}_2 \leq 93\%$  on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

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Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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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 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 14:56:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 14:56:31
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4)	18 Sep 2020 14:56:31
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 14:56:22
User entered empty.	Elisa Moralez (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4)	18 Sep 2020 14:56:22
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4)	18 Sep 2020 14:56:22
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4)	18 Sep 2020 14:56:22
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4)	18 Sep 2020 14:56:22
	(b) (4)	



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Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:59:27

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:08
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Sep 2020 14:56:22



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:59:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:25
User entered 'No (N)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:45:36
User entered 'Yes (Y)'	Frances Saubon (b) (4)	16 Sep 2020 18:25:37



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Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:09:54



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Time of Contact](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 19:17:10
Query 'Data is required. Please complete.' answered with 'time is unknown' (Site from System).	Frances Saubon (b) (4)	19 Nov 2020 16:10:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 16:09:54
User entered empty.	System	19 Nov 2020 16:09:54
	Frances Saubon (b) (4)	19 Nov 2020 16:09:54
	(b) (4)	



**US3322061**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 26 Nov 2020 10:59:27**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 16:09:54



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Frances Saubon (b) (4) Scheduled)'	(b) (4)	19 Nov 2020 16:09:54



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	19 Nov 2020 16:10:05
User entered 'No (N)'	Frances Saubon (b) (4)	19 Nov 2020 16:09:54



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Date of Test](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasal Swab (Nasal Swab)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



US3322061

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



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Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:12:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 16:12:55
User entered 'No (N)' reason for change: Data Entry Error	Frances Saubon (b) (4)	19 Nov 2020 16:12:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:12:47
User entered empty.	Frances Saubon (b) (4)	19 Nov 2020 16:12:47



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Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



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Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:59:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:12:47



**US3322061**

**Folder: Covid-19 Assessment 14 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 26 Nov 2020 10:59:27**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 16:12:47



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 10:59:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 10:59:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:59:49
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:28:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:28:58
User entered 'No (N)' reason for change: Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 21:28:58
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 01:48:26
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:59:49
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 10:59:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:30:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:30:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 21:30:36
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 01:48:26
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	18 Sep 2020 21:30:36
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 10:59:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 21:00:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:59:16
Query 'Data is required. Please complete.' answered with 'Day 9 has not happened yet. The following fields will be updated once source is completed.' (Site from System).	Frances Saubon (b) (4)	18 Sep 2020 21:39:52
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 01:48:26
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 21:00:04
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 10:59:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Frances Saubon (b) (4)	25 Sep 2020 22:59:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:59:20
Query 'Data is required. Please complete.' answered with 'Day 14 has not happened yet. The following fields will be updated once source is completed.' (Site from System).	Frances Saubon (b) (4)	18 Sep 2020 21:42:03
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 01:48:26
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:59:27**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 10:59:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	21 Oct 2020 15:25:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Sep 2020 06:59:22
Query 'Data is required. Please complete.' answered with 'Day 21 has not happened yet. Data will be updated once source is completed.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:59:22
Query 'Data is required. Please complete.' answered with 'Day 21 has not happened yet. Data will be updated once source is completed.' (Site from System).	Frances Saubon (b) (4)	18 Sep 2020 21:46:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 01:48:26
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:59:27**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	17 Sep 2020 01:48:26



US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 10:59:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	21 Oct 2020 15:25:39
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 happened yet. Data will be updated once source is completed.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:59:24
User opened query 'Data is required. Please complete.' (Site from System).	Frances Saubon (b) (4)	18 Sep 2020 21:47:30
	(b) (4)	
User entered empty.	System	17 Sep 2020 01:48:26
	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4)	21 Oct 2020 15:25:39
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:48:26



**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:27**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:44:14



US3322061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:28:53
User entered '11 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:44:14



US3322061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

[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 20:28:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Sep 2020 01:44:14



**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:27**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	17 Sep 2020 01:44:14



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '11 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '16:30'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '11 Sep 2020 16:30'	System	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '66.0' in	(b) (4), (b) (6)	17 Sep 2020 01:45:38
DataPoint set to visible.	System	17 Sep 2020 01:44:14



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '145.0' lb	(b) (4), (b) (6)	17 Sep 2020 01:45:38
DataPoint set to visible.	System	17 Sep 2020 01:44:14



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
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)	25 Sep 2020 13:39:42
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.' answered with 'NCS' (Site from System).	Blessing Felix-Okoroji (b) (4)	24 Sep 2020 20:03:45
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	17 Sep 2020 01:45:38
User entered '96.4' F	(b) (4), (b) (6)	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '74'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '18'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '119'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '85'	(b) (4), (b) (6)	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:46:43



US3322061

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:29:42
User entered '11 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:46:43



US3322061

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 26 Nov 2020 10:59:27**

[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 20:30:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:46:55



US3322061

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:59:27

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:30:02
User entered '11 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:46:55



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:19:32



US3322061

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:19:32



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:27

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)	21 Oct 2020 13:19:32



**US3322061**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 10:59:27**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	21 Oct 2020 13:19:32



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '14:42'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



**US3322061**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '14 Oct 2020 14:42'	System	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '66' in	Frances Saubon (b) (4)	21 Oct 2020 13:21:19
DataPoint set to visible.	(b) (4) System	21 Oct 2020 13:19:32



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '150' lb	Frances Saubon (b) (4)	21 Oct 2020 13:21:19
DataPoint set to visible.	(b) (4) System	21 Oct 2020 13:19:32



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Pulse (xxx)

Audit	User	Time (GMT)
User entered '66'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



**US3322061**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 10:59:27**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

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

Audit	User	Time (GMT)
User entered '12'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:19



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Oct 2020 13:21:19



US3322061

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 10:59:27**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:37



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:37



US3322061

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:59:27

[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 14OCT2020 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 08:35:33
Query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 14OCT2020 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 'Noted, a DCF will be submitted to reflect correct data change. Thank you.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	02 Nov 2020 19:15:52
User opened query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 14OCT2020 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 10:17:59
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:57



US3322061

**Folder: Convalescence Visit Day 28 (1)**

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

**Generated On: 26 Nov 2020 10:59:27**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:57



US3322061

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:29:18



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:05
User entered 'USA-US060-2020-mRNA-1273-P301000002'	System	17 Sep 2020 15:54:57
User entered 'New'	(b) (4), (b) (6)	17 Sep 2020 15:54:57



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (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)	30 Sep 2020 12:51:52
Data point term sent to Coder	System	29 Sep 2020 18:31:42
Coding entries removed.	Frances Saubon (b) (4)	29 Sep 2020 18:30:58
User entered 'Symptomatic Covid -19' reason for change: Data Entry Error	Frances Saubon (b) (4)	29 Sep 2020 18:30:58
User closed query 'PV Query: Please consider updating event term to COVID-19, given diagnosis was confirmed by the subject's clinical presentation and RT-PCR test.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 18:01:26
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:00:47
Data point term sent to Coder	System	22 Sep 2020 20:59:34
Query 'PV Query: Please consider updating event term to COVID-19, given diagnosis was confirmed by the subject's clinical presentation and RT-PCR test.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4)	22 Sep 2020 20:58:57
Coding entries removed.	Frances Saubon (b) (4)	22 Sep 2020 20:58:51
User entered 'Covid-19' reason for change: Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 20:58:51
User opened query 'PV Query: Please consider updating event term to COVID-19, given diagnosis was confirmed by the subject's clinical presentation and RT-PCR test.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 13:41:04
User coded data point as SOC: Investigations, HLT: 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)	17 Sep 2020 05:22:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 05:22:53
Data point term sent to Coder	System	17 Sep 2020 01:33:24



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Symptomatic confirmed positive COVID-19 case'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[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 13:22:24
Comment added 'Withdrawn because subject tested positive for COVID-19 before second dose of IP. Per guidelines, subjects will be withdrawn when this occurs.'	Elisa Moralez (b) (4)	18 Sep 2020 14:58:24
Comment added 'Withdrawn because subject tested positive for COVID-19 before second dose of IP. Per guidelines, subjects will be withdrawn when this occurs.'	Elisa Moralez (b) (4)	18 Sep 2020 14:58:24
Comment added 'dose was withdrawn due to COVID19 positive test'.	(b) (4), (b) (6)	17 Sep 2020 01:33:42
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	17 Sep 2020 01:32:39
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

Action taken with investigational product

Audit	User	Time (GMT)
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)	02 Oct 2020 08:25:23
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)	28 Sep 2020 05:33:06
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 'due to testing positive with COVID-19' (Site from System).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:36:11
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'done, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:35:58
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	25 Sep 2020 14:34:56
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 11:55:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[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)	26 Oct 2020 18:01:39
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 'please see updated indications for conmeds, source has been updated and we have now matched data to updates' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 19:01:01
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 16:12:12
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: "Concomitant Procedure" is checked as Yes, however no Concomitant Procedure has been entered. Please add missing Concomitant Procedure or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 08:35:50
Query 'Per CDM: "Concomitant Procedure" is checked as Yes, however no Concomitant Procedure has been entered. Please add missing Concomitant Procedure or clarify otherwise. Thank you!' answered with 'data error, thank you, since been corrected to match source. There was no concomitant procedure' (Site from DM).	Elisa Moralez (b) (4)	09 Oct 2020 21:13:58
User entered '0' reason for change: Data Entry Error	(b) (4)	09 Oct 2020 21:13:31
User opened query 'Per CDM: "Concomitant Procedure" is checked as Yes, however no Concomitant Procedure has been entered. Please add missing Concomitant Procedure or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:03:14
User entered '1' reason for change: Data Entry Error	Frances Saubon (b) (4)	29 Sep 2020 18:30:58
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:27

[Narrative](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	29 Sep 2020 18:30:58
User entered 'Subject was contacted on 11 Sept 2020 for a routine weekly COVID-19 symptom surveillance call. During the call she reported having a headache, congestion and runny nose, so she was asked to come into clinic for assessment. Nasal swab sample was collected on 11 Sep 2020, and upon examination, no upper respiratory or lung abnormalities were seen. Subject was notified of positive SARS-CoV-2 Ab results after we received them earlier today. She reportedly last experienced any symptoms yesterday. Local health department was called to report confirmed COVID-19 positive case and forms are being submitted. Subject is currently in New Jersey. I called her a few times this evening but have been unable to reach her to speak to her personally. I left a voicemail requesting a call back and will attempt to reach her again tomorrow.'	(b) (4), (b) (6)	17 Sep 2020 01:32:39



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR-RQ: Response noted. However, please include the response update of ipsilateral on the term or update term to Injection site Lymphadenopathy. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:05:57
User closed query 'Per DM CLR - RQ: Site's response noted. However, it was not confirmed if this was Ipsilateral-same side of vaccination site or Contralateral-opposite side of vaccination site. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 18:09:50
Query 'Per DM CLR - RQ: Site's response noted. However, it was not confirmed if this was Ipsilateral-same side of vaccination site or Contralateral-opposite side of vaccination site. Please review and update accordingly. ' answered with 'ipsilateral, as it was on left side, same side as injection noted in exposure form' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:22:43
User opened query 'Per DM CLR - RQ: Site's response noted. However, it was not confirmed if this was Ipsilateral-same side of vaccination site or Contralateral-opposite side of vaccination site. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 00:49:16
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary lymph nodes enlarged - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:37:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:37:50
User closed query 'Per DM CLR - RQ: Site's response noted. However, please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:22:45
Data point term sent to Coder	System	09 Nov 2020 20:16:27



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. However, please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' answered with 'Please see updated term' (Site from DM). Coding entries removed.	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:16:04
User entered 'AXILLARY LYMPHADENOPATHY, Left axilla' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:15:43
User opened query 'Per DM CLR - RQ: Site's response noted. However, please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 00:12:52
User closed query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy and provide the location of underarm swelling.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 00:12:47
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:14:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:14:04
Data point term sent to Coder	System	30 Oct 2020 20:56:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy and provide the location of underarm swelling.' answered with 'please see updated term' (Site from DM). Coding entries removed.	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 20:56:04
	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 20:55:33
User entered 'Axillary Lymphadenopathy' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 20:55:33
User opened query 'Per DM CLR: Please review if this is a lymphadenopathy. If so, please update term to lymphadenopathy and include the location (eg, injection site lymphadenopathy, etc). Else, provide comment in query response to confirm this is not lymphadenopathy and provide the location of underarm swelling.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:48:59
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Swelling, LLT: Local swelling - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:19:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:19:49
Data point term sent to Coder	System	07 Oct 2020 14:57:50
User closed query 'For coding purposes, please split UNDERARM SWELLING/TENDERNESS into separate entries' (Site from System).	System	07 Oct 2020 14:57:04
Query 'For coding purposes, please split UNDERARM SWELLING/TENDERNESS into separate entries' answered with 'completing now, thank you' (Site from System).	Elisa Moralez (b) (4) (b) (4)	07 Oct 2020 14:57:04
User entered 'UNDERARM SWELLING' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	07 Oct 2020 14:56:52
User opened query 'For coding purposes, please split UNDERARM SWELLING/TENDERNESS into separate entries' (Site from System).	Coder Import (b) (4) (b) (4)	30 Sep 2020 07:48:41
Data point term sent to Coder	System	25 Sep 2020 14:34:12
User entered 'underarm swelling/tenerness'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Sep 2020 18:32:20
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	29 Sep 2020 18:32:20
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'form will not be marked as completed without an entry for time, time in source is unknown' (Site from System).	Elisa Moralez (b) (4)	25 Sep 2020 14:34:24
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	25 Sep 2020 14:33:44
User entered '00:00'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:59:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 18:32:20
User entered '27 Aug 2020 00:00'	System	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	29 Sep 2020 18:32:20
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	29 Sep 2020 18:32:20
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'form will not be marked as completed without an entry for time, time in source is unknown' (Site from System).	Elisa Moralez (b) (4)	25 Sep 2020 14:34:27
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	25 Sep 2020 14:33:44
User entered '00:00'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:59:27**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 18:32:20
User entered '28 Aug 2020 00:00'	System	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)' reason for change: Data Entry Error	Frances Saubon (b) (4)	29 Sep 2020 18:32:20
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

None

Audit	User	Time (GMT)
User entered '1'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



US3322061

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:27

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:33:44



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 14:33:44



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Sep 2020 14:33:44



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 26 Nov 2020 10:59:27**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm medication dosed for Indication COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:00:43
Query 'Per ETRTR: Please confirm medication dosed for Indication COVID-19, thanks.' answered with 'entered' (Site from CRA).	Elisa Moralez (b) (4)	28 Sep 2020 16:20:03
User opened query 'Per ETRTR: Please confirm medication dosed for Indication COVID-19, thanks.' (Site from CRA).	(b) (4)	
User opened query 'Per ETRTR: Please confirm medication dosed for Indication COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 00:14:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:34:54



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 03:18:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 03:18:46
Data point term sent to Coder	System	17 Sep 2020 01:37:25
User entered 'Effexor XR'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hot Flashes'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '37.5'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Sep 2020 01:37:03
User entered 'UN Jun 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 01:37:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Sep 2020 01:36:45
User entered '00 Jun 2020' (non-conformant).	(b) (4), (b) (6)	17 Sep 2020 01:36:45



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:36:45



**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 01:36:45



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 01:36:45



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:27

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 01:39:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 01:39:45
Data point term sent to Coder	System	17 Sep 2020 01:39:26
User entered 'Multivitamin'	(b) (4), (b) (6) (b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:23:48
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	06 Nov 2020 15:22:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	06 Nov 2020 15:22:41
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:44:12
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Indication](#)

Audit	User	Time (GMT)
User entered 'Supplements'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)' reason for change:	Frances Saubon (b) (4)	22 Sep 2020 20:57:32
Data Entry Error	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:59:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per DMR: "If Dose unit is Other, specify" is recorded as 'TABLER', however, dose unit 'tablet' is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:20:08
Query 'Per DMR: "If Dose unit is Other, specify" is recorded as 'TABLER', however, dose unit 'tablet' is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	22 Sep 2020 20:57:39
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 20:57:32
User opened query 'Per DMR: "If Dose unit is Other, specify" is recorded as 'TABLER', however, dose unit 'tablet' is provided in the ecrf dropdown. Kindly verify if the dose unit can be selected from the drop down options, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:01:04
User entered 'tablet'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered 'UN Jan 2010'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:39:15



**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 01:39:15



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 01:39:15



**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 01:39:15



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:27

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: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 15:49:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 15:49:33
Data point term sent to Coder Coding entries removed.	System	09 Nov 2020 15:48:44
	Frances Saubon (b) (4)	09 Nov 2020 15:48:25
User entered 'Acetaminophen' reason for change: Data Entry Error	Frances Saubon (b) (4)	09 Nov 2020 15:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:25:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 19:25:29
Data point term sent to Coder Coding entries removed.	System	22 Oct 2020 18:59:51
	Elisa Moralez (b) (4)	22 Oct 2020 18:59:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 01:42:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 01:42:48
Data point term sent to Coder User entered 'Tylenol'	System	17 Sep 2020 01:41:27
	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:27

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:41:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'updated indication to match edited source' (Site from DM).	Elisa Moralez (b) (4)	22 Oct 2020 18:59:26
User entered 'symptomatic covid-19' reason for change: New Information	(b) (4)	22 Oct 2020 18:59:14
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:06:38
User entered 'Headache'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:27

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:42:05
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected thank you' (Site from DM).	Elisa Moralez (b) (4)	22 Oct 2020 18:59:46
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 18:59:40
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:06:04
User entered 'mL (mL)'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '07 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:27

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Ongoing = "Yes", however corresponding AE "SYMPTOMATIC COVID-19" resolved on 15 Sep 2020. Kindly review if end date for this CM should be updated appropriately, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:13:35
Query 'Per CDM: Ongoing = "Yes", however corresponding AE "SYMPTOMATIC COVID-19" resolved on 15 Sep 2020. Kindly review if end date for this CM should be updated appropriately, else provide clarification.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 15:48:45
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	09 Nov 2020 15:48:25
User opened query 'Per CDM: Ongoing = "Yes", however corresponding AE "SYMPTOMATIC COVID-19" resolved on 15 Sep 2020. Kindly review if end date for this CM should be updated appropriately, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:17:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '15 Sep 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4)	09 Nov 2020 15:48:25
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:40:59



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:40:59



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:27

[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: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:00:31
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 10:00:31
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 18:59:52 22 Oct 2020 18:58:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 12:41:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 12:41:33
Data point term sent to Coder User entered 'Theraflu (Acetaminophen, Dextromethorphan, Phenylephrine HCL)'	System (b) (4), (b) (6)	17 Sep 2020 01:42:28 17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:27

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:42:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'thank you' (Site from DM).	Elisa Moralez (b) (4)	22 Oct 2020 18:59:00
User entered 'symptomatic covid-19' reason for change: New Information	Elisa Moralez (b) (4)	22 Oct 2020 18:58:54
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:49:01
User entered 'Congestion/Runny nose'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'TEA BAG'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:27

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:27

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query ' Per CDM: Ongoing = "Yes", however corresponding AE "SYMPTOMATIC COVID-19" resolved on 15 Sep 2020. Kindly review if end date for this CM should be updated appropriately, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:13:54
Query ' Per CDM: Ongoing = "Yes", however corresponding AE "SYMPTOMATIC COVID-19" resolved on 15 Sep 2020. Kindly review if end date for this CM should be updated appropriately, else provide clarification.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 16:03:20
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	09 Nov 2020 16:03:14
User opened query ' Per CDM: Ongoing = "Yes", however corresponding AE "SYMPTOMATIC COVID-19" resolved on 15 Sep 2020. Kindly review if end date for this CM should be updated appropriately, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:18:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4)	09 Nov 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 01:42:14



**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 10:59:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 01:42:14



US3322061

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 26 Nov 2020 10:59:27**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 18:49:35



US3322061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:27

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:32:10
User entered '16 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:34:56



US3322061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:32:10
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 09:28:29
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) (b) (4)	30 Sep 2020 14:34:48
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 09:29:12
User entered 'Due to SARS-COV-2 (COVID)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:34:56



US3322061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:27

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:32:10
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:34:56



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:27

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 12:16:50
Query 'Data is required. Please complete.' answered with 'This form was filled out in error, the patient is still receiveing follow-up visits from us to check on their symptoms and COVID-19 related questions. The have ceased dosing, but not ended study procedures for dealing with AEs.' (Site from System).	Elisa Moralez (b) (4)	25 Sep 2020 14:46:59
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 14:45:53
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	25 Sep 2020 14:45:53
User entered '16 Sep 2020'	Elisa Moralez (b) (4)	25 Sep 2020 14:35:40



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:27

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 12:16:52
Query 'Data is required. Please complete.' answered with 'This form was filled out in error, the patient is still receiveing follow-up visits from us to check on their symptoms and COVID-19 related questions. The have ceased dosing, but not ended study procedures for dealing with AEs.' (Site from System).	Elisa Moralez (b) (4)	25 Sep 2020 14:46:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	25 Sep 2020 14:45:53
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Elisa Moralez (b) (4)	25 Sep 2020 14:45:53
	(b) (4)	
	Elisa Moralez (b) (4)	25 Sep 2020 14:35:40
	(b) (4)	



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:27

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	25 Sep 2020 14:45:53
User entered 'Subject tested positive for COVID-19'	Elisa Moralez (b) (4)	25 Sep 2020 14:35:40



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:27

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:35:40



US3322061

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 26 Nov 2020 10:59:27**

If main cause of death is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:35:40



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:27

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:35:40



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:27

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 14:35:40



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'USA-US060-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Veronica'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Fragoso'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered '6550 Mapleridge Street'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Houston'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'TX'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered '77081'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 18:01:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:53:32
User entered 'US' (non-conformant).	System	17 Sep 2020 15:55:54



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 18:02:00
User entered '1'	System	17 Sep 2020 15:55:54



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'USA-US060-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Veronica'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Fragoso'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered '6550 Mapleridge Street'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Houston'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'TX'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered '77081'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 18:01:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:53:32
User entered 'US' (non-conformant).	System	17 Sep 2020 15:55:54



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 18:02:00
User entered '1'	System	17 Sep 2020 15:55:54



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '17/Sep/2020 11:55'	System	17 Sep 2020 15:55:54



US3322061

Folder: SAE USA-US060-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 18:01:49
User entered 'I'	(b) (4), (b) (6)	17 Sep 2020 15:55:54



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'USA-US060-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

**Serious**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'No (N)'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Veronica'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Fragoso'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered '6550 Mapleridge Street'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'Houston'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered 'TX'	System	17 Sep 2020 15:54:57



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:55:46
User entered '77081'	System	17 Sep 2020 15:54:57



US3322061

Folder: SAE USA-US060-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:27

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 18:01:49
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:53:32
User entered 'US' (non-conformant).	System	17 Sep 2020 15:55:54



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 26 Nov 2020 10:59:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 18:02:00
User entered '1'	System	17 Sep 2020 15:55:54



**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 26 Nov 2020 10:59:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Sep/2020 14:01'	System	23 Sep 2020 18:02:00



US3322061

Folder: SAE USA-US060-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 18:02:00