

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

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:15:45

All time stamps listed in this document are displayed in GMT

US3322061

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 02:09:11

Generated On: 11 Aug 2021 22:15:45

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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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Condition	ABDOMINOPLASTY, ELECTIVE
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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☒  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2008

Date of last menstruation unknown False



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 02:09:14

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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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

(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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

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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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

<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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45

**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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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 VISIT2

US3322061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Confirmed COVID-19 <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
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 <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
<hr/>	
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: 11 Aug 2021 22:15:45

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

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

**US3322061**

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

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:15:45**

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

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322061

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments



US3322061

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322061

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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 VISIT3

US3322061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

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

US3322061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

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 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

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

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

US3322061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 110

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

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

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

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

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

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

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 145

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

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

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

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

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

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

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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14 JAN 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 13:38:39

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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:44:31

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: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 06:58:25
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 08:31:46

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: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 06:32:09
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 08:30:37

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: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 13:21:35
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 15:33:19

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 07:07:31

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 MAR 2021 12:00:38
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 08:09:56

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

<b>TIMEPOINT</b>	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 12:00:36
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: 11 Aug 2021 22:15:45

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 09:44:49
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 17:16:10

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 08:21:37

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Date and time of submission

03 MAY 2021 16:24:02

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 264

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Open Date & Time](#)

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13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 320

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

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

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

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

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

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

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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

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

11 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

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

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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 <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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 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: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	14 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

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30 DEC 2021 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 JAN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 JAN 2022 00:01

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27 JAN 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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03 FEB 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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 ☐

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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 ☐

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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03 MAR 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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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: 11 Aug 2021 22:15:45

**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 ☐

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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24 MAR 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 11 Aug 2021 22:15:45

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="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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 691

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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"/>

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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04 AUG 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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07 AUG 2022 00:01

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11 AUG 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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25 AUG 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**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: 11 Aug 2021 22:15:45**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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: 11 Aug 2021 22:15:45

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59



US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3322061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3322061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:15:45

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 13:21:43

US3322061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322061

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322061

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

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 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 23:44:57

Generated On: 11 Aug 2021 22:15:45

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3322061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

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 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 23:44:57

Generated On: 11 Aug 2021 22:15:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

13:25 (24 HR)

Collection date and time (derived)

12 MAR 2021 13:25

US3322061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:21:02

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

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 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:21:02

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3322061**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3322061**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 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"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 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"/>

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EAB) (1725)

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Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 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"/>
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Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	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"/>
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Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	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"/>
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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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

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

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Symptom Day

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

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

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

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	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"/>
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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (17)

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Symptom Day

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

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Form: Symptom Log (17)

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Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 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"/>
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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Data signed: (b) (4) 30 Apr 2021 22:26:04

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (18)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	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: Symptom Log (19)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	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: Symptom Log (21)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	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"/>

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Data signed: (b) (4) 30 Apr 2021 22:26:04

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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 \_\_\_\_\_

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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

**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

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

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

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 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

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

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: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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

Visit date (dd MMM yyyy)	15 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3322061

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Date of updated informed consent ( <i>dd MMM yyyy</i> )	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	15 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3322061

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3322061

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	15 JAN 2021
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 15:05
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3322061

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	15 JAN 2021
Time of assessment (00:00-23:59)	16:27 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 16:27
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3322061

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

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 JAN 2021

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

US3322061

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

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 JAN 2021

What was the treatment time? (00:00-23:59) 15:48 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 15:48

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

What was the frequency of the study treatment dosing? ONCE

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

US3322061

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 JAN 2021

Collection time (00:00-23:59)

15:33 (24 HR)

Collection date and time (derived)

15 JAN 2021 15:33

US3322061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	15:28
Collection Date and Time (derived)	15 JAN 2021 15:28

US3322061

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

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

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 OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:14

Generated On: 11 Aug 2021 22:15:45

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

US3322061

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 14:49
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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)	11 FEB 2021
Time of assessment (00:00-23:59)	16:24 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 16:24
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3322061

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3322061

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 15:45 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 15:45

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

US3322061

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

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 OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322061

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57



US3322061

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3322061

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 21:52:41

Generated On: 11 Aug 2021 22:15:45

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

13:25 (24 HR)

Collection date and time (derived)

12 MAR 2021 13:25

US3322061

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

---

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)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

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"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

AEID

Adverse event

IPSILATERAL INJECTION SITE  
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 ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

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

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US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

---

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)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

Name of Medication EFFEXOR XR

Prophylaxis Yes ☐  
No ☒

Indication HOT FLASHES

Dose per administration 37.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN 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)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENTS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 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)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

	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)		07 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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

Name of Medication THERAFLU (ACETOMINOPHEN,  
DEXTROMETHORPHAN,PHENY  
LEPHRINE HCL)

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify TEA BAG

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

	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 Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 19:25:58

Generated On: 11 Aug 2021 22:15:45

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

US3322061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 02:09:12

Generated On: 11 Aug 2021 22:15:45

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3322061

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

Date of dosing discontinuation (dd MMM yyyy) 16 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

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

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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)

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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
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



US3322061

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

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Feb 2021 02:09:13

Generated On: 11 Aug 2021 22:15:45

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: 11 Aug 2021 22:15:45**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'US3322061'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:59:17

US3322061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:47:47

US3322061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	(b) (4)	
	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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	21 Aug 2020 18:47:47

US3322061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User entered 'SCRN'	System	21 Aug 2020 18:47:47

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:59:19



US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '57'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:15:45**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'YEARS'	System	21 Aug 2020 18:48:11

**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:15:45**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '57'	System	21 Aug 2020 16:53:26

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Female (F)'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:15:45**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'I'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11



US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

US3322061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:15:45

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:15:45**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

**US3322061**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:15:45**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:11

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Aug 2020'	System	21 Aug 2020 16:53:26



US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2020'	System	21 Aug 2020 16:53:26

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Amendment 2 (2)'	Elisa Moralez (b) (4)	21 Aug 2020 16:53:26

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 16:53:26

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 16:53:26

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 16:53:26

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 16:53:26

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:59:18

US3322061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:15:45

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'I'	System	21 Aug 2020 16:53:35



US3322061

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 16:53:35

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Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:15:45

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:32

US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User coded data point as SOC: Nervous system disorders, HLGT: 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

US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 1994'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:47

US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:47

US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:47

**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:48:47

US3322061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:15:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:48:47



**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1994'	System	21 Aug 2020 18:48:47

**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1994'	System	21 Aug 2020 18:48:47

**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:48:47

**US3322061**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:48:47

US3322061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM).	(b) (4) (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).		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).		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) (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) (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) (b) (4)	29 Sep 2020 14:10:32
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 14:10:20
User entered 'Left KNEE ARTHROSCOPY' reason for change: New Information	Elisa Moralez (b) (4) (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

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:15:45

[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).		23 Sep 2020 16:03:29
User coded data point as SOC: Investigations, HLT: 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: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 1992'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:06

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:06



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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:06

**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 1992'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:06

**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:06

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1992'	System	21 Aug 2020 18:49:06

**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1992'	System	21 Aug 2020 18:49:06

**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1992'	System	21 Aug 2020 18:49:06

**US3322061**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1992'	System	21 Aug 2020 18:49:06

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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



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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 1999'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:25

**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:15:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:25

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:25

**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 1999'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:25

**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:25

**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1999'	System	21 Aug 2020 18:49:25

**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1999'	System	21 Aug 2020 18:49:25

**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1999'	System	21 Aug 2020 18:49:25



**US3322061**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1999'	System	21 Aug 2020 18:49:25

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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 18:49:40

**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2001'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:40

US3322061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:40

**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:15:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:40

**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2001'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:40

US3322061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:15:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:49:40

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2001'	System	21 Aug 2020 18:49:40



**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2001'	System	21 Aug 2020 18:49:40

**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2001'	System	21 Aug 2020 18:49:40

**US3322061**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2001'	System	21 Aug 2020 18:49:40

US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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) (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) (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) (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) (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) (b) (4)	22 Sep 2020 16:16:31
User entered 'BILATERAL TUBAL LIGATION' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 16:16:31

US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: 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
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 'Tubal Ligation'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:00
	(b) (4)	

**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2001'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:00

**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:00

**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:00



**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2001'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:00

**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:00

**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2001'	System	21 Aug 2020 18:50:00

**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2001'	System	21 Aug 2020 18:50:00

US3322061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2001'	System	21 Aug 2020 18:50:00

**US3322061**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2001'	System	21 Aug 2020 18:50:00

US3322061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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

**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2010'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:34



**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:34

US3322061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:34

**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2010'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:34

**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:34

**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2010'	System	21 Aug 2020 18:50:34

**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2010'	System	21 Aug 2020 18:50:34

**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2010'	System	21 Aug 2020 18:50:34

**US3322061**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2010'	System	21 Aug 2020 18:50:34



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Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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

US3322061

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2004'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:51

US3322061

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:51

**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:15:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:51

**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2004'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:51

**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:50:51

US3322061

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:15:45

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2004'	System	21 Aug 2020 18:50:51

**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2004'	System	21 Aug 2020 18:50:51



**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2004'	System	21 Aug 2020 18:50:51

**US3322061**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2004'	System	21 Aug 2020 18:50:51

US3322061

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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

**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 1967'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:06

US3322061

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:06

US3322061

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:06

**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:51:06

**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:06



**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1967'	System	21 Aug 2020 18:51:06

**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1967'	System	21 Aug 2020 18:51:06

**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:06

**US3322061**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:06

US3322061

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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.	(b) (4) Coder Import (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: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2001'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:19

**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:15:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:19

**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:15:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:19



**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:51:19

**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:19

**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2001'	System	21 Aug 2020 18:51:19

**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2001'	System	21 Aug 2020 18:51:19

US3322061

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:19

**US3322061**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:19

US3322061

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 1990'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:30



US3322061

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:30

US3322061

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:30

**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:51:30

**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:30

**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1990'	System	21 Aug 2020 18:51:30

**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1990'	System	21 Aug 2020 18:51:30

US3322061

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:30

**US3322061**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:30



US3322061

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (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)	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)	21 Aug 2020 18:51:45

**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2008'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:45

**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:45

US3322061

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:45

**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:51:45

**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:51:45

**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2008'	System	21 Aug 2020 18:51:45

**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2008'	System	21 Aug 2020 18:51:45



**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:45

**US3322061**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	21 Aug 2020 18:51:45

US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:15:45

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User coded data point as SOC: Social circumstances, HLT: 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

**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2008'	Frances Saubon (b) (4)	22 Sep 2020 16:17:06

US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Frances Saubon (b) (4)	22 Sep 2020 16:17:06

US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:15:45

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Frances Saubon (b) (4)	22 Sep 2020 16:17:06

**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 16:17:06

US3322061

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:15:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Frances Saubon (b) (4)	22 Sep 2020 16:17:06



**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2008'	System	22 Sep 2020 16:17:06

**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2008'	System	22 Sep 2020 16:17:06

**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	22 Sep 2020 16:17:06

**US3322061**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered empty.	System	22 Sep 2020 16:17:06

US3322061

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:15:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43

**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:15:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43



**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: 11 Aug 2021 22:15:45

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	29 Oct 2020 16:34:43

**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1992'	System	29 Oct 2020 16:34:43

**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1992'	System	29 Oct 2020 16:34:43

**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 1992'	System	29 Oct 2020 16:34:43

**US3322061**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '1992'	System	29 Oct 2020 16:34:43

US3322061

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:15:45

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:40:55
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) (b) (4)	13 Jan 2021 12:38:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Jan 2021 12:38:58
Data point term sent to Coder	System	12 Jan 2021 22:17:02
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'This procedure was elective. A "tummy tuck"' (Site from DM).	Blessing Felix-Okoroji (b) (4)	12 Jan 2021 22:16:50
Coding entries removed.	Blessing Felix-Okoroji (b) (4)	12 Jan 2021 22:16:30
User entered 'ABDOMINOPLASTY, elective' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	12 Jan 2021 22:16:30
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)	10 Jan 2021 07:16:26
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) (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) (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) (b) (4)	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2004'	Frances Saubon (b) (4)	29 Oct 2020 18:47:12



US3322061

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Frances Saubon (b) (4)	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Frances Saubon (b) (4)	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2004'	Frances Saubon (b) (4)	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Frances Saubon (b) (4)	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2004'	System	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2004'	System	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered 'Jan 2004'	System	29 Oct 2020 18:47:12

**US3322061**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User entered '2004'	System	29 Oct 2020 18:47:12



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (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) (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).	System	21 Aug 2020 18:52:25
User entered '21 Aug 2020'	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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) (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).		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: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '66' in	Elisa Moralez (b) (4)	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: 11 Aug 2021 22:15:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '154.4' lb	Elisa Moralez (b) (4)	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: 11 Aug 2021 22:15:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
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: 11 Aug 2021 22:15:45

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
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: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Other (Other)'	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	(b) (4) System	21 Aug 2020 18:52:56
User entered missing code ND - Not Done; reason for change New Information	Elisa Moralez (b) (4) (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).	System	21 Aug 2020 18:52:25
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User entered 'bpm'	System	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User entered 'breaths/min'	System	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25



US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User entered 'mmHg'	System	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User entered 'mmHg'	System	21 Aug 2020 18:52:25

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47

US3322061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47

US3322061

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:53:07

US3322061

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:53:07

US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:45

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 18:53:59
User entered '20 Aug 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (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) (b) (4)	21 Aug 2020 18:53:28



US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:45

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:53:28

US3322061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:45

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
Comment added 'Data updated'.	(b) (4)	
	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)	21 Sep 2020 14:07:40
	(b) (4)	
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)	21 Aug 2020 18:53:28
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:45

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:53:28

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:45

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:53:28

**US3322061**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:15:45**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:53:28

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:45

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN UNK 2008'	Elisa Moralez (b) (4)	21 Aug 2020 18:53:28

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Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:15:45

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:41:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:53:28

US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

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**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

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**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44



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Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered (b) (6)	(b) (4) Elisa Moralez (b) (4)	21 Aug 2020 18:54:56
(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
: retired, but sees (b) (4) 10-25 patients one day per week		

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).

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'I'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

US3322061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:15:45

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:43:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:54:44

US3322061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Per GCL Lab Reconciliation Re-query: Swab: Please enter data in Covid-19 Assessment Folder.' (Site from DM).	(b) (4) (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).		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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[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: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:55:11

US3322061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	21 Aug 2020 18:55:11



**US3322061**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'VISIT1'	System	21 Aug 2020 18:55:11

US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:39:25

US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '106726'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:39:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:39:25

US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:55:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:55:23

US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:55:23

**US3322061**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:55:23



US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:55:23

US3322061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Frances Saubon (b) (4)	21 Sep 2020 19:23:59
Amendment Manager: DataPoint set to visible.	System	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: 11 Aug 2021 22:15:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
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: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '8:48'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered '21 Aug 2020 8:48'	System	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '97.0' F	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '66'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'bpm'	System	21 Aug 2020 18:57:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'breaths/min'	System	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '112'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'mmHg'	System	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '81'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'mmHg'	System	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
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: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

**US3322061**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '12:15'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
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: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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) (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.' answered with 'NCS' (Site from System).		17 Sep 2020 18:49:19
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) (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '62'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'bpm'	System	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'breaths/min'	System	21 Aug 2020 18:57:00

US3322061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '141'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'mmHg'	System	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '82'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:00

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'mmHg'	System	21 Aug 2020 18:57:00



US3322061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:05

US3322061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:05

US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 16:54:05

US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 16:54:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 16:54:05

US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 16:54:05

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 16:54:05

US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11:42'	Elisa Moralez (b) (4)	21 Aug 2020 16:54:05



US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered '21 Aug 2020 11:42'	System	21 Aug 2020 16:54:05

US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4)	21 Aug 2020 16:54:05

US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'ONCE'	System	21 Aug 2020 16:54:05

US3322061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 16:54:05

US3322061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:19

US3322061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:19

US3322061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11:30'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:19

**US3322061**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:15:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
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: 11 Aug 2021 22:15:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '21 Aug 2020'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:28

US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
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: 11 Aug 2021 22:15:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:28

US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:15:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11:26'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:28

**US3322061**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
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: 11 Aug 2021 22:15:45

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
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: 11 Aug 2021 22:15:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:28

US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Aug 2020 18:57:28



US3322061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:15:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered empty.	System	21 Aug 2020 18:57:28

US3322061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Aug 2020 18:57:33

US3322061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'I'	System	21 Aug 2020 18:57:33

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'Yes (Y)'	System	21 Aug 2020 17:15:40
	System	21 Aug 2020 17:15:40

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '96.5'	System	21 Aug 2020 17:15:40
	System	21 Aug 2020 17:15:40

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'Yes (Y)'	System	22 Aug 2020 03:29:07
	System	22 Aug 2020 03:29:07

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '97.0'	System	22 Aug 2020 03:29:07
	System	22 Aug 2020 03:29:07

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '21 Aug 2020 22:29'	System	22 Aug 2020 03:29:07
	System	22 Aug 2020 03:29:07

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'Yes (Y)'	System	23 Aug 2020 04:41:07
	System	23 Aug 2020 04:41:07

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '97.5'	System	23 Aug 2020 04:41:07
	System	23 Aug 2020 04:41:07

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	23 Aug 2020 04:41:07
	System	23 Aug 2020 04:41:07

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '22 Aug 2020 23:41'	System	23 Aug 2020 04:41:07
	System	23 Aug 2020 04:41:07

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'Yes (Y)'	System	24 Aug 2020 00:44:24
	System	24 Aug 2020 00:44:24

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '97.8'	System	24 Aug 2020 00:44:24
	System	24 Aug 2020 00:44:24

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'Yes (Y)'	System	24 Aug 2020 22:53:13
	System	24 Aug 2020 22:53:13

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '96.6'	System	24 Aug 2020 22:53:13
	System	24 Aug 2020 22:53:13

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '24 Aug 2020 18:53'	System	24 Aug 2020 22:53:13
	System	24 Aug 2020 22:53:13

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'Yes (Y)'	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: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '25 Aug 2020 18:13'	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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '97.6'	System	27 Aug 2020 01:13:24
	System	27 Aug 2020 01:13:24



US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'Yes (Y)'	System	28 Aug 2020 01:53:19
	System	28 Aug 2020 01:53:19

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:45

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '97.6'	System	28 Aug 2020 01:53:19
	System	28 Aug 2020 01:53:19

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '27 Aug 2020 20:53'	System	28 Aug 2020 01:53:19
	System	28 Aug 2020 01:53:19

US3322061

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	21 Aug 2020 17:15:49
	System	21 Aug 2020 17:15:49

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '23 Aug 2020 19:44'	System	24 Aug 2020 00:44:36
	System	24 Aug 2020 00:44:36

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (1)'	System	24 Aug 2020 22:53:24
	System	24 Aug 2020 22:53:24

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	24 Aug 2020 22:53:24
	System	24 Aug 2020 22:53:24

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '24 Aug 2020 18:53'	System	24 Aug 2020 22:53:24
	System	24 Aug 2020 22:53:24

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	25 Aug 2020 22:14:08
	System	25 Aug 2020 22:14:08

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	25 Aug 2020 22:14:08
	System	25 Aug 2020 22:14:08

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (1)'	System	25 Aug 2020 22:14:08
	System	25 Aug 2020 22:14:08



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '25 Aug 2020 18:14'	System	25 Aug 2020 22:14:08
	System	25 Aug 2020 22:14:08

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (1)'	System	27 Aug 2020 01:13:40
	System	27 Aug 2020 01:13:40

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	27 Aug 2020 01:13:40
	System	27 Aug 2020 01:13:40

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	27 Aug 2020 01:13:40
	System	27 Aug 2020 01:13:40

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (1)'	System	27 Aug 2020 01:13:40
	System	27 Aug 2020 01:13:40



US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '26 Aug 2020 21:13'	System	27 Aug 2020 01:13:40
	System	27 Aug 2020 01:13:40

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	28 Aug 2020 01:52:04
	System	28 Aug 2020 01:52:04

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '27 Aug 2020 20:52'	System	28 Aug 2020 01:52:04
	System	28 Aug 2020 01:52:04

US3322061

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	21 Aug 2020 17:16:09
	System	21 Aug 2020 17:16:09

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	21 Aug 2020 17:16:09
	System	21 Aug 2020 17:16:09

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	21 Aug 2020 17:16:09
	System	21 Aug 2020 17:16:09

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	21 Aug 2020 17:16:09
	System	21 Aug 2020 17:16:09



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	21 Aug 2020 17:16:09
	System	21 Aug 2020 17:16:09

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	21 Aug 2020 17:16:09
	System	21 Aug 2020 17:16:09

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	21 Aug 2020 17:16:09
	System	21 Aug 2020 17:16:09

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:15:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	22 Aug 2020 03:29:38
	System	22 Aug 2020 03:29:38



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	22 Aug 2020 03:29:38
	System	22 Aug 2020 03:29:38

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	22 Aug 2020 03:29:38
	System	22 Aug 2020 03:29:38

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	22 Aug 2020 03:29:38
	System	22 Aug 2020 03:29:38

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	22 Aug 2020 03:29:38
	System	22 Aug 2020 03:29:38

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	22 Aug 2020 03:29:38
	System	22 Aug 2020 03:29:38

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '21 Aug 2020 22:29'	System	22 Aug 2020 03:29:38
	System	22 Aug 2020 03:29:38

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47

**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:15:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47

**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:15:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '22 Aug 2020 23:41'	System	23 Aug 2020 04:41:47
	System	23 Aug 2020 04:41:47

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53

**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:15:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53

**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:15:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '23 Aug 2020 19:44'	System	24 Aug 2020 00:44:53
	System	24 Aug 2020 00:44:53

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 22:53:39
	System	24 Aug 2020 22:53:39

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 22:53:39
	System	24 Aug 2020 22:53:39

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 22:53:39
	System	24 Aug 2020 22:53:39

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 22:53:39
	System	24 Aug 2020 22:53:39

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 22:53:39
	System	24 Aug 2020 22:53:39

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	24 Aug 2020 22:53:39
	System	24 Aug 2020 22:53:39

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	25 Aug 2020 22:14:22
	System	25 Aug 2020 22:14:22

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	25 Aug 2020 22:14:22
	System	25 Aug 2020 22:14:22

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	25 Aug 2020 22:14:22
	System	25 Aug 2020 22:14:22

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	25 Aug 2020 22:14:22
	System	25 Aug 2020 22:14:22

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	25 Aug 2020 22:14:22
	System	25 Aug 2020 22:14:22



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:15:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	25 Aug 2020 22:14:22
	System	25 Aug 2020 22:14:22

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57



US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57

**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:15:45**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57

**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:15:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '26 Aug 2020 21:13'	System	27 Aug 2020 01:13:57
	System	27 Aug 2020 01:13:57

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (0)'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16



**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:15:45**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '27 Aug 2020 20:52'	System	28 Aug 2020 01:52:16
	System	28 Aug 2020 01:52:16

US3322061

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'No (N)'	System	30 Aug 2020 01:29:06
	System	30 Aug 2020 01:29:06

US3322061

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:45

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '29 Aug 2020 20:29'	System	30 Aug 2020 01:29:06
	System	30 Aug 2020 01:29:06

US3322061

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered 'None (1)'	System	30 Aug 2020 01:29:21
	System	30 Aug 2020 01:29:21

**US3322061**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(9)**

**Generated On: 11 Aug 2021 22:15:45**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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' User entered '29 Aug 2020 20:29'	System	30 Aug 2020 01:29:21
	System	30 Aug 2020 01:29:21



US3322061

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 11 Aug 2021 22:15:45

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:15:24
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: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Sep 2020 13:17:09

US3322061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	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 Morales (b) (4) (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 Morales (b) (4) (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 Morales (b) (4) (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 Morales (b) (4) (b) (4)	09 Sep 2020 13:17:09

US3322061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Contact Not Made (CONTACT NOT MADE)'	Elisa Moralez (b) (4)	09 Sep 2020 13:17:09

**US3322061**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '3 unsuccessful attempt to contact subject'	Elisa Moralez (b) (4)	09 Sep 2020 13:17:09

US3322061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Sep 2020 13:17:50

US3322061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'I'	System	09 Sep 2020 13:17:50



**US3322061**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Sep 2020 13:18:24

US3322061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: 11 Aug 2021 22:15:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	09 Sep 2020 13:18:24

**US3322061**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	09 Sep 2020 13:18:24

US3322061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Sep 2020 13:18:28

**US3322061**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:40:14
User entered 'I'	System	09 Sep 2020 13:18:28

**US3322061**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 20:58:50

US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11 Sep 2020'	Elisa Moralez (b) (4)	11 Sep 2020 20:58:50



US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	11 Sep 2020 20:58:50

US3322061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 20:58:50

US3322061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 20:58:54

US3322061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'I'	System	11 Sep 2020 20:58:54

US3322061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Jan 2021 19:52:44

**US3322061**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:52:44

US3322061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:52:44

**US3322061**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'VISIT2'	System	25 Jan 2021 19:52:44



US3322061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:10:33

US3322061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'I'	System	22 Jan 2021 19:10:33

**US3322061**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	22 Jan 2021 19:10:45

US3322061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:10:45

US3322061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:10:45

US3322061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:10:45

US3322061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:10:49

**US3322061**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'I'	System	22 Jan 2021 19:10:49



**US3322061**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	22 Jan 2021 19:10:58

US3322061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:10:58

US3322061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:10:58

US3322061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:10:58

US3322061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:03

**US3322061**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'I'	System	22 Jan 2021 19:11:03

US3322061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:09

US3322061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:09



US3322061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:09

US3322061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:09

US3322061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:15

**US3322061**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'I'	System	22 Jan 2021 19:11:15

**US3322061**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Jan 2021 19:42:13

US3322061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:42:13

**US3322061**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:42:13

**US3322061**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'VISIT3'	System	25 Jan 2021 19:42:13



US3322061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:23

**US3322061**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'I'	System	22 Jan 2021 19:11:23

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 64'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 16:54:05

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 71'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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DataPoint Inactivated.	System	25 Sep 2020 14:35:40

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

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**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

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Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

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**Generated On: 11 Aug 2021 22:15:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



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

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

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

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

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**Generated On: 11 Aug 2021 22:15:45**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

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**Generated On: 11 Aug 2021 22:15:45**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**US3322061**

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

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**Generated On: 11 Aug 2021 22:15:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**Folder: Safety Follow Up Diary (1)**

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
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DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

**Folder: 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.](#)

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US3322061

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
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**US3322061**

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

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DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 16:54:05

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 78'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 16:54:05

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered 'Day 92'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 16:54:05

US3322061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:15:45

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:17:58
DataPoint Activated.	System	25 Sep 2020 14:45:53
DataPoint Inactivated.	System	25 Sep 2020 14:35:40
Data entry locked.	System	21 Aug 2020 16:54:05
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 16:54:05

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-18T13:38:32', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6cd9d492-8c48-4361-a4e3-a9004e8fbd9c' User entered 'No (N)'	System	18 Jan 2021 19:38:43
	System	18 Jan 2021 19:38:43

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-18T13:38:35', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6cd9d492-8c48-4361-a4e3-a9004e8fbd9c' User entered 'No (N)'	System	18 Jan 2021 19:38:43

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-18T13:38:39', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6cd9d492-8c48-4361-a4e3-a9004e8fbd9c' User entered '18 Jan 2021 13:38:39'	System	18 Jan 2021 19:38:43
	System	18 Jan 2021 19:38:43

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-25T12:44:18', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '36564e4f-58ce-4d16-a3fa-d920ab2d9087' User entered 'No (N)'	System	25 Jan 2021 18:44:33
	System	25 Jan 2021 18:44:33

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-25T12:44:27', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '36564e4f-58ce-4d16-a3fa-d920ab2d9087'	System	25 Jan 2021 18:44:33
User entered 'No (N)'	System	25 Jan 2021 18:44:33

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-25T12:44:31', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '36564e4f-58ce-4d16-a3fa-d920ab2d9087' User entered '25 Jan 2021 12:44:31'	System	25 Jan 2021 18:44:33
	System	25 Jan 2021 18:44:33

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-31T06:58:19', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '062f756f-c48c-44db-88f1-c52b154b2e8e' User entered 'No (N)'	System	31 Jan 2021 12:58:30
	System	31 Jan 2021 12:58:30



**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-31T06:58:22', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '062f756f-c48c-44db-88f1-c52b154b2e8e'	System	31 Jan 2021 12:58:30
User entered 'No (N)'	System	31 Jan 2021 12:58:30

**US3322061**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-01-31T06:58:25', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '062f756f-c48c-44db-88f1-c52b154b2e8e' User entered '31 Jan 2021 06:58:25'	System	31 Jan 2021 12:58:30
	System	31 Jan 2021 12:58:30

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-07T08:31:40', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'b7da3a9f-65cd-4631-afcc-5aca984f9d4b' User entered 'No (N)'	System	07 Feb 2021 14:31:48
	System	07 Feb 2021 14:31:48

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-07T08:31:42', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'b7da3a9f-65cd-4631-afcc-5aca984f9d4b' User entered 'No (N)'	System	07 Feb 2021 14:31:48
	System	07 Feb 2021 14:31:48

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-07T08:31:46', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'b7da3a9f-65cd-4631-afcc-5aca984f9d4b'	System	07 Feb 2021 14:31:48
User entered '07 Feb 2021 08:31:46'	System	07 Feb 2021 14:31:48



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-14T06:32:02', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '36bbfec5-f782-47ed-90f4-4c66b0a8327c' User entered 'No (N)'	System	14 Feb 2021 12:32:12
	System	14 Feb 2021 12:32:12

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-14T06:32:05', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '36bbfec5-f782-47ed-90f4-4c66b0a8327c'	System	14 Feb 2021 12:32:12
User entered 'No (N)'	System	14 Feb 2021 12:32:12

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-14T06:32:09', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '36bbfec5-f782-47ed-90f4-4c66b0a8327c' User entered '14 Feb 2021 06:32:09'	System	14 Feb 2021 12:32:12
	System	14 Feb 2021 12:32:12

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-21T08:30:32', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0a1ad9e2-a1ec-456f-b3ee-103b4341b25e' User entered 'No (N)'	System	21 Feb 2021 13:30:40
	System	21 Feb 2021 13:30:40

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-21T08:30:34', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0a1ad9e2-a1ec-456f-b3ee-103b4341b25e' User entered 'No (N)'	System	21 Feb 2021 13:30:40
	System	21 Feb 2021 13:30:40

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-21T08:30:37', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '0a1ad9e2-a1ec-456f-b3ee-103b4341b25e' User entered '21 Feb 2021 08:30:37'	System	21 Feb 2021 13:30:40
	System	21 Feb 2021 13:30:40

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-28T07:21:28-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7d776616-5fd4-43da-a91c-0b3cb2e09b9b' User entered 'No (N)'	System	28 Feb 2021 13:21:37
	System	28 Feb 2021 13:21:37



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-28T07:21:32-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7d776616-5fd4-43da-a91c-0b3cb2e09b9b'	System	28 Feb 2021 13:21:37
User entered 'No (N)'	System	28 Feb 2021 13:21:37

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-28T07:21:35-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '7d776616-5fd4-43da-a91c-0b3cb2e09b9b' User entered '28 Feb 2021 13:21:35'	System	28 Feb 2021 13:21:37
	System	28 Feb 2021 13:21:37

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-08T15:33:14-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9dcf2e6f-8538-4e0b-b4cc-a8bb6ff17fd3'	System	08 Mar 2021 21:33:21
User entered 'No (N)'	System	08 Mar 2021 21:33:21

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-08T15:33:16-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9dcf2e6f-8538-4e0b-b4cc-a8bb6ff17fd3'	System	08 Mar 2021 21:33:21
User entered 'No (N)'	System	08 Mar 2021 21:33:21

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-08T15:33:19-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '9dcf2e6f-8538-4e0b-b4cc-a8bb6ff17fd3' User entered '08 Mar 2021 15:33:19'	System	08 Mar 2021 21:33:21
	System	08 Mar 2021 21:33:21



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-14T07:07:25-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '50d2660f-0c0b-49f1-8845-0fa8ec66b5c9'	System	14 Mar 2021 12:07:35
User entered 'No (N)'	System	14 Mar 2021 12:07:35

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-14T07:07:27-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '50d2660f-0c0b-49f1-8845-0fa8ec66b5c9'	System	14 Mar 2021 12:07:35
User entered 'No (N)'	System	14 Mar 2021 12:07:35

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-14T07:07:31-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '50d2660f-0c0b-49f1-8845-0fa8ec66b5c9' User entered '14 Mar 2021 07:07:31'	System	14 Mar 2021 12:07:35
	System	14 Mar 2021 12:07:35

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-23T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6d114194-2a47-4218-8a6c-f30b40f6645a' User entered 'Yes (Y)'	System	23 Mar 2021 17:01:10
	System	23 Mar 2021 17:01:10

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-23T12:00:30-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6d114194-2a47-4218-8a6c-f30b40f6645a'	System	23 Mar 2021 17:01:10
User entered 'No (N)'	System	23 Mar 2021 17:01:10

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-23T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6d114194-2a47-4218-8a6c-f30b40f6645a'	System	23 Mar 2021 17:01:10
User entered 'No (N)'	System	23 Mar 2021 17:01:10

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-23T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6d114194-2a47-4218-8a6c-f30b40f6645a'	System	23 Mar 2021 17:01:10
User entered 'No (N)'	System	23 Mar 2021 17:01:10

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-23T12:00:38-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '6d114194-2a47-4218-8a6c-f30b40f6645a' User entered '23 Mar 2021 12:00:38'	System	23 Mar 2021 17:01:10
	System	23 Mar 2021 17:01:10

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-28T08:09:51-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '465bafba-bde8-490e-98a8-a8bea5963b97'	System	28 Mar 2021 13:10:01
User entered 'No (N)'	System	28 Mar 2021 13:10:01

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-28T08:09:53-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '465bafba-bde8-490e-98a8-a8bea5963b97'	System	28 Mar 2021 13:10:01
User entered 'No (N)'	System	28 Mar 2021 13:10:01

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-03-28T08:09:56-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '465bafba-bde8-490e-98a8-a8bea5963b97'	System	28 Mar 2021 13:10:01
User entered '28 Mar 2021 08:09:56'	System	28 Mar 2021 13:10:01

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-06T12:00:30-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'd43c234b-75cc-4291-9c9e-10f428878519'	System	06 Apr 2021 16:01:47
User entered 'No (N)'	System	06 Apr 2021 16:01:47



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-06T12:00:34-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'd43c234b-75cc-4291-9c9e-10f428878519'	System	06 Apr 2021 16:01:47
User entered 'No (N)'	System	06 Apr 2021 16:01:47

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-06T12:00:36-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'd43c234b-75cc-4291-9c9e-10f428878519'	System	06 Apr 2021 16:01:47
User entered '06 Apr 2021 12:00:36'	System	06 Apr 2021 16:01:47

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-11T09:44:40-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'a37f41a6-ed6f-4b02-95c4-cebab014fb20'	System	11 Apr 2021 14:44:54
User entered 'No (N)'	System	11 Apr 2021 14:44:54

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-11T09:44:43-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'a37f41a6-ed6f-4b02-95c4-cebab014fb20'	System	11 Apr 2021 14:44:54
User entered 'No (N)'	System	11 Apr 2021 14:44:54

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-11T09:44:49-05:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'a37f41a6-ed6f-4b02-95c4-cebab014fb20'	System	11 Apr 2021 14:44:54
User entered '11 Apr 2021 09:44:49'	System	11 Apr 2021 14:44:54



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-19T17:16:04-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'e37510f5-dc2b-4b4b-b0ef-d9211107d477'	System	19 Apr 2021 21:16:12
User entered 'No (N)'	System	19 Apr 2021 21:16:12

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-19T17:16:06-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'e37510f5-dc2b-4b4b-b0ef-d9211107d477'	System	19 Apr 2021 21:16:12
User entered 'No (N)'	System	19 Apr 2021 21:16:12

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-19T17:16:10-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'e37510f5-dc2b-4b4b-b0ef-d9211107d477'	System	19 Apr 2021 21:16:12
User entered '19 Apr 2021 17:16:10'	System	19 Apr 2021 21:16:12

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-25T08:21:31-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '733c5b58-384d-4396-ac6f-89dca3b2b6f7' User entered 'No (N)'	System	25 Apr 2021 12:21:41
	System	25 Apr 2021 12:21:41

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-25T08:21:34-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '733c5b58-384d-4396-ac6f-89dca3b2b6f7'	System	25 Apr 2021 12:21:41
User entered 'No (N)'	System	25 Apr 2021 12:21:41

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-04-25T08:21:37-04:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '733c5b58-384d-4396-ac6f-89dca3b2b6f7'	System	25 Apr 2021 12:21:41
User entered '25 Apr 2021 08:21:37'	System	25 Apr 2021 12:21:41

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-05-03T16:23:56-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'd68ca2a3-0121-4152-84e8-906e4de3039d'	System	03 May 2021 22:24:09
User entered 'No (N)'	System	03 May 2021 22:24:09



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-05-03T16:23:59-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'd68ca2a3-0121-4152-84e8-906e4de3039d'	System	03 May 2021 22:24:09
User entered 'No (N)'	System	03 May 2021 22:24:09

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-05-03T16:24:02-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: 'd68ca2a3-0121-4152-84e8-906e4de3039d'	System	03 May 2021 22:24:09
User entered '03 May 2021 16:24:02'	System	03 May 2021 22:24:09

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Feb 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: 11 Aug 2021 22:15:45**

**TIMEPOINT**

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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Feb 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: 11 Aug 2021 22:15:45**

[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 Feb 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Feb 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: 11 Aug 2021 22:15:45**

[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 Mar 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Mar 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: 11 Aug 2021 22:15:45**

[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 Mar 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Mar 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Mar 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: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Apr 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: 11 Aug 2021 22:15:45**

**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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 May 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: 11 Aug 2021 22:15:45**

[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



**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Jun 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: 11 Aug 2021 22:15:45**

[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 Jun 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: 11 Aug 2021 22:15:45**

**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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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Jun 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: 11 Aug 2021 22:15:45**

[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 Jun 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Jun 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: 11 Aug 2021 22:15:45**

[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 Jun 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 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: 11 Aug 2021 22:15:45**

[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 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 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: 11 Aug 2021 22:15:45**

[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 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 Jul 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: 11 Aug 2021 22:15:45**

[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 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: 11 Aug 2021 22:15:45**

**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

**US3322061**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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 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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

**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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:15:45**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-28T07:21:40-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '961a1bb2-c0eb-45c8-9ead-d0b672d0094d'	System	28 Feb 2021 13:21:45
User entered 'No (N)'	System	28 Feb 2021 13:21:45

**US3322061**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (20864BCE-AB63-435B-820B-079B33BD9DCE)', Time: '2021-02-28T07:21:43-06:00', User OID: 'PatientReportedOutcome (US3322061)', ODM File OID: '961a1bb2-c0eb-45c8-9ead-d0b672d0094d' User entered '28 Feb 2021 13:21:43'	System	28 Feb 2021 13:21:45
	System	28 Feb 2021 13:21:45

**US3322061**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:34

US3322061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:34

US3322061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:34



**US3322061**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:34

US3322061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:38

**US3322061**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	07 Apr 2021 09:26:57
User entered 'I'	System	22 Jan 2021 19:11:38

**US3322061**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:54

US3322061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:54

**US3322061**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:54

US3322061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:11:54

US3322061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:11:45



**US3322061**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User entered 'I'	System	22 Jan 2021 19:11:45

**US3322061**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:12:03

US3322061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '20 Jan 2021'	Elisa Moralez (b) (4)	22 Jan 2021 19:12:03

US3322061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	22 Jan 2021 19:12:03

US3322061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:12:03

US3322061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:12:12

**US3322061**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:08
User entered 'I'	System	22 Jan 2021 19:12:12

**US3322061**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Feb 2021 19:24:45



US3322061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '19 Feb 2021'	Elisa Moralez (b) (4)	21 Feb 2021 19:24:45

US3322061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	21 Feb 2021 19:24:45

US3322061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	21 Feb 2021 19:24:45

US3322061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Feb 2021 19:24:51

US3322061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered 'I'	System	21 Feb 2021 19:24:51

US3322061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User closed query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' (Site from DM).		30 Mar 2021 18:06:22
Query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' answered with 'THANKS' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	29 Mar 2021 22:06:58
User opened query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:25:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 21:52:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 21:04:30

**US3322061**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered '12 Mar 2021'	Elisa Moralez (b) (4)	12 Mar 2021 21:04:30

US3322061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	12 Mar 2021 21:04:30



**US3322061**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered 'VISIT4'	System	12 Mar 2021 21:04:30

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered 'No (N)'	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

**US3322061**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered empty.	System	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52



US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered empty.	System	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered empty.	System	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered empty.	System	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User entered empty.	Elisa Moralez (b) (4)	29 Mar 2021 22:06:52

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered empty.	System	29 Mar 2021 22:06:52



US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12

US3322061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12

US3322061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Mar 2021 21:04:49

US3322061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:04:49

US3322061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D57 it is captured. Please clarify why there is a difference or update the field. Thank you!' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:25:24
Query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D57 it is captured. Please clarify why there is a difference or update the field. Thank you!' ' answered with 'updated, thank you!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	26 Mar 2021 20:23:40
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	26 Mar 2021 20:23:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	26 Mar 2021 20:23:25
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D57 it is captured. Please clarify why there is a difference or update the field. Thank you!' ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 18:31:05
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 21:52:41
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 21:04:53

US3322061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
Signature has been broken.	Elisa Moralez (b) (4)	26 Mar 2021 20:23:25
User entered '12 Mar 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4)	26 Mar 2021 20:23:25
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:04:53

US3322061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
Signature has been broken.	Elisa Moralez (b) (4)	26 Mar 2021 20:23:25
User entered '13:25' reason for change: Data Entry Error	Elisa Moralez (b) (4)	26 Mar 2021 20:23:25
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:04:53

US3322061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered '12 Mar 2021 13:25'	System	26 Mar 2021 20:23:25
User entered empty.	System	12 Mar 2021 21:04:53



US3322061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	12 Mar 2021 21:04:57

**US3322061**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:37:12
User entered 'I'	System	12 Mar 2021 21:04:57

**US3322061**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:21:02
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 15:34:22
	(b) (4)	

US3322061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:21:02
	(b) (4)	
User entered '19 Apr 2021'	Elisa Morales (b) (4)	23 Apr 2021 15:34:22
	(b) (4)	

**US3322061**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:21:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 15:34:22
	(b) (4)	

US3322061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:21:02
User entered empty.	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 15:34:22
	(b) (4)	

US3322061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:21:02
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	23 Apr 2021 15:34:38
	(b) (4)	

**US3322061**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 15:34:38



US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:15:45

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:26:47
User entered '11 Sep 2020'	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: 11 Aug 2021 22:15:45

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:42
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: 11 Aug 2021 22:15:45

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 2 (Day 2)'	(b) (4)	
	Frances Saubon (b) (4)	16 Sep 2020 19:20:12
	(b) (4)	

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
User entered '12 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:24:57
User entered '14 Sep 2020'	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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
User entered '97' reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:45:56
User entered empty.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
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: 11 Aug 2021 22:15:45

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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) (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) (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) (b) (4)	18 Sep 2020 20:45:56
User entered empty.	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:08:51
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: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 3 (Day 3)'	(b) (4)	
	Frances Saubon (b) (4)	16 Sep 2020 19:24:57
	(b) (4)	

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered '98' reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:46:41
User entered empty.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	18 Sep 2020 20:46:41
User entered empty.	System	16 Sep 2020 19:24:57



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered '98.4' F reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:46:41
User entered empty.	Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:12:32
User entered 'None (None)' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Sep 2020 19:35:01
User entered empty.	(b) (4) Frances Saubon (b) (4)	16 Sep 2020 19:24:57

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 4 (Day 4)'	(b) (4)	
	Frances Saubon (b) (4)	16 Sep 2020 19:41:46
	(b) (4)	

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
User entered '97' reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:04
User entered empty.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
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: 11 Aug 2021 22:15:45

Temperature

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
User entered '97.5' F reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:04
User entered empty.	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46



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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	16 Sep 2020 19:41:46

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:14:33
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: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 5 (Day 5)'	(b) (4)	
	Frances Saubon (b) (4)	16 Sep 2020 19:44:01
	(b) (4)	



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
User entered '98' reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:15
User entered empty.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
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: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
User entered '97.6' F reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:15
User entered empty.	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:18:11
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 (5)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 6 (Day 6)'	(b) (4)	
	Frances Saubon (b) (4)	16 Sep 2020 19:44:48
	(b) (4)	

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
User entered '98' reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:25
User entered empty.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
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: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
User entered '97.3' F reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:25
User entered empty.	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:20:27
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: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 7 (Day 7)'	(b) (4)	
	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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
User entered '100' reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:33
User entered empty.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	18 Sep 2020 20:47:33
User entered empty.	System	17 Sep 2020 21:59:01



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
User entered '97.2' F reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (b) (4)	18 Sep 2020 20:47:33
User entered empty.	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:21:18
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 (7)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 1 (Day 1)'	(b) (4) 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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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)	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)	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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
User entered '0'	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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	18 Sep 2020 14:52:35

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:29:02
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 (8)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 12 (Day 12)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 8 (Day 8)'	(b) (4)	
	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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
User entered '0'	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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
User entered '99' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:54:35
User entered missing code ND - Not Done.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
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: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
User entered '97.2' F reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:54:35
User entered missing code ND - Not Done.	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:31:12
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 (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 9 (Day 9)'	(b) (4)	
	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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered '19 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered '98'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:32:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:55:53

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 14 (Day 14)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:02:54
User entered 'Day 10 (Day 10)'	(b) (4)	
	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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered '20 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered '100'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	21 Sep 2020 20:57:17



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17



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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:33:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:57:17

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:03:31
User entered 'Day 11 (Day 11)'	(b) (4)	
	Frances Saubon (b) (4)	22 Sep 2020 15:46:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

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[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
User entered '21 Sep 2020'	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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
User entered '0'	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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
User entered '99'	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	22 Sep 2020 15:46:24

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
User entered '98.2' F	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:35:09
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 (12)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 16 (Day 16)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:03:31
User entered 'Day 12 (Day 12)'	(b) (4)	
	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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
User entered '0'	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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
User entered '99'	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	23 Sep 2020 22:00:42

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
User entered '97.6' F	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:37:19
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 (13)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 17 (Day 17)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:03:31
User entered 'Day 13 (Day 13)'	(b) (4)	
	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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 22:31:11
Data hard unlocked.		03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	30 Apr 2021 22:26:04
DataPoint Un-verified.	(b) (4) Elisa Moralez (b) (4)	30 Apr 2021 19:01:58
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	30 Apr 2021 19:01:58
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	30 Apr 2021 19:01:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 20:13:13
User closed query 'Please consider updating date to 24Sept20 as this is the day noted in source as when the call took place.' (Site from CRA).		19 Feb 2021 20:13:10
Query 'Please consider updating date to 24Sept20 as this is the day noted in source as when the call took place.' answered with 'ok' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	18 Feb 2021 20:07:31
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	18 Feb 2021 20:07:26
User entered '24 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Feb 2021 20:07:26
DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 16:18:31
User opened query 'Please consider updating date to 24Sept20 as this is the day noted in source as when the call took place.' (Site from CRA).		12 Feb 2021 16:17:40
User closed query 'Please provide source for 23Sep20. Per source 23Sep20 was not performed.' (Site from CRA).		12 Feb 2021 16:17:40
Query 'Please provide source for 23Sep20. Per source 23Sep20 was not performed.' answered with 'please see day 13 of illness telemed visits, the date is entered as 23-sep-2020' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	10 Feb 2021 22:19:55

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
User opened query 'Please provide source for 23Sep20. Per source 23Sep20 was not performed.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 20:43:12
User entered '23 Sep 2020'	Frances Saubon (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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered '99'	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	24 Sep 2020 21:25:46

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:18:31
User entered 'None (None)'	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 (17)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 18 (Day 18)' reason for change:	(b) (4)	
Data Entry Error	Frances Saubon (b) (4)	29 Sep 2020 19:05:58
User entered 'Day 15 (Day 15)' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	29 Sep 2020 16:04:56
User entered 'Day 14 (Day 14)'	(b) (4)	
	Frances Saubon (b) (4)	25 Sep 2020 22:58:27
	(b) (4)	

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 22:31:23
Data hard unlocked.		03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	30 Apr 2021 22:26:04
DataPoint Un-verified.	(b) (4)	
	Elisa Moralez (b) (4)	30 Apr 2021 19:02:08
Signature has been broken.	(b) (4)	
	Elisa Moralez (b) (4)	30 Apr 2021 19:02:08
	(b) (4)	
User entered '24 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	30 Apr 2021 19:02:08
User signature succeeded.	(b) (4)	
	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 20:46:24
User entered '25 Sep 2020'		
	Frances Saubon (b) (4)	25 Sep 2020 22:58:27
	(b) (4)	

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
User entered '0'	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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered '%'	System	25 Sep 2020 22:58:27

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:46:24
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: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 2 (Day 2)'	(b) (4) 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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
User entered '8 Sep 2020'	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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered empty.	System	29 Sep 2020 16:01:05

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:00
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 (19)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 3 (Day 3)'	(b) (4) 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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
User entered '9 Sep 2020'	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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
User entered 'I'	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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
User entered empty.	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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered empty.	System	29 Sep 2020 16:01:14

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
User entered empty.	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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:02
User entered empty.	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 (20)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 4 (Day 4)'	(b) (4) 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: 11 Aug 2021 22:15:45

[Date](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
User entered 'I'	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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered empty.	System	29 Sep 2020 16:01:35

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 20:47:04
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 (21)

Generated On: 11 Aug 2021 22:15:45

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Day 5 (Day 5)'	(b) (4) 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: 11 Aug 2021 22:15:45

Date

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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) (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) (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) (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: 11 Aug 2021 22:15:45

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'I'	(b) (4) 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: 11 Aug 2021 22:15:45

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
User entered empty.	System	29 Sep 2020 16:02:04

US3322061

Folder: Covid-19 Assessment 11 Sep 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:15:45

[Temperature](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Chills](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Cough](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Fatigue](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Body Aches](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Headache](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Nausea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Vomiting](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 20:06:54
Data hard locked.		01 May 2021 21:44:48
DataPoint Verified.		02 Mar 2021 17:14:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) 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: 11 Aug 2021 22:15:45

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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).		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).		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: 11 Aug 2021 22:15:45

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered empty.	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: 11 Aug 2021 22:15:45

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered empty.	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: 11 Aug 2021 22:15:45

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:27:21
User entered empty.	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

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:44:56
User entered 'I'	System	16 Sep 2020 20:34:29

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Folder: Covid-19 Assessment 11 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:15:45

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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

Generated On: 11 Aug 2021 22:15:45

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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Generated On: 11 Aug 2021 22:15:45

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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) (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) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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Generated On: 11 Aug 2021 22:15:45

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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

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[Start Date](#)

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DataPoint Verified.	(b) (4) (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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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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DataPoint Verified.	(b) (4) (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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DataPoint Verified.	(b) (4) (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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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Generated On: 11 Aug 2021 22:15:45

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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Generated On: 11 Aug 2021 22:15:45

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:45:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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)'	(b) (4) Frances Saubon (b) (4)	16 Sep 2020 18:25:37



**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User accepted default value 'Day 3 (Day 3)'		17 Sep 2020 01:48:26

**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
User entered 'Yes (Y)'		17 Sep 2020 01:48:26

US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:15:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated "13SEP2020" is reported under Illness Visits 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).		14 Dec 2020 09:23:32
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 13SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).		14 Dec 2020 09:23:06
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated "13SEP2020" is reported under Illness Visits 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 'corrected' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:37:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 13SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'corrected' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:37:22
User entered '13 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:37:15

US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:15:45

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated "13SEP2020" is reported under Illness Visits 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)	11 Dec 2020 08:34:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14SEP2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 13SEP2020 in PPD Central lab. Please confirm the correct Date in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM).		11 Dec 2020 07:09:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14,16,17,20SEP2020 is recorded under Illness Visit Day 3,5,7,9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		09 Dec 2020 08:49:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14,16,17,20SEP2020 is recorded under Illness Visit Day 3,5,7,9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession number now being updated in PPD logs.' (Site from DM).		04 Dec 2020 16:30:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14,16,17,20SEP2020 is recorded under Illness Visit Day 3,5,7,9 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		04 Dec 2020 11:16:46

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User accepted default value 'Day 5 (Day 5)'		17 Sep 2020 01:48:26

US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:15:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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).	(b) (4)	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).	(b) (4)	17 Sep 2020 01:48:26
User entered empty.	System	17 Sep 2020 01:48:26

**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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: 11 Aug 2021 22:15:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User accepted default value 'Day 7 (Day 7)'		17 Sep 2020 01:48:26

US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:15:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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)	17 Sep 2020 01:48:26

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:15:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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: 11 Aug 2021 22:15:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User accepted default value 'Day 9 (Day 9)'		17 Sep 2020 01:48:26

US3322061

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:15:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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: 11 Aug 2021 22:15:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	26 Feb 2021 11:07:01
	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' answered with '1F609ON' (Site from DM).	Elisa Moralez (b) (4)	25 Jan 2021 18:26:43
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM). User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:08:58
	(b) (4), (b) (6)	25 Jan 2021 07:08:58
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'shipped 21-Sep-2020' (Site from DM).	Elisa Moralez (b) (4)	11 Jan 2021 15:59:11
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Jan 2021 10:10:23
	(b) (4), (b) (6)	15 Dec 2020 21:55:28
User entered '20 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 21:00:04

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**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:15:45**

[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 (5)**

**Generated On: 11 Aug 2021 22:15:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User accepted default value 'Day 14 (Day 14)'		17 Sep 2020 01:48:26



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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:15:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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: 11 Aug 2021 22:15:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
User entered empty.		17 Sep 2020 01:48:26

**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:15:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User accepted default value 'Day 21 (Day 21)'		17 Sep 2020 01:48:26

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:15:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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) (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) (b) (4)	18 Sep 2020 21:46:55
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: 11 Aug 2021 22:15:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
User entered empty.		17 Sep 2020 01:48:26

**US3322061**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:15:45**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User accepted default value 'Day 28 (Day 28)'		17 Sep 2020 01:48:26

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:15:45

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:55:28
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), (b) (6)	21 Sep 2020 06:59:24
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).	Frances Saubon (b) (4)	18 Sep 2020 21:47:30
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 (7)

Generated On: 11 Aug 2021 22:15:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:31
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM). User signature succeeded.	(b) (4)	26 Feb 2021 11:08:22
	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' answered with '1F609ON' (Site from DM).	Elisa Moralez (b) (4)	25 Jan 2021 18:26:54
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM). User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:09:50
		25 Jan 2021 07:09:50
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'shipped 16-Oct-2020' (Site from DM).	Elisa Moralez (b) (4)	11 Jan 2021 15:59:56
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). Data hard unlocked.	(b) (4), (b) (6)	10 Jan 2021 10:11:21
		10 Jan 2021 10:11:16
Data hard locked.		10 Jan 2021 10:11:13



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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:15:45

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 21:55:28
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14OCT2020 is recorded under Illness Visit Day 28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		09 Dec 2020 08:51:09
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14OCT2020 is recorded under Illness Visit Day 28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession number now being updated in PPD logs.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:33:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14OCT2020 is recorded under Illness Visit Day 28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		04 Dec 2020 11:17:07
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) (4), (b) (6)	17 Sep 2020 01:48:26

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:28:53
User entered 'Yes (Y)'		17 Sep 2020 01:44:14

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:28:53
User entered '11 Sep 2020'		17 Sep 2020 01:44:14

US3322061

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (U) (4), (b) (6)	02 Nov 2020 20:28:53
User entered 'Clinic (Clinic)'		17 Sep 2020 01:44:14

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:03
User entered 'SICKD1'	System	17 Sep 2020 01:44:14

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered 'Yes (Y)'		17 Sep 2020 01:45:38

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '11 Sep 2020'		17 Sep 2020 01:45:38

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '16:30'		17 Sep 2020 01:45:38



**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
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: 11 Aug 2021 22:15:45**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '66.0' in		17 Sep 2020 01:45:38
DataPoint set to visible.		17 Sep 2020 01:44:14

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '145.0' lb		17 Sep 2020 01:45:38
DataPoint set to visible.		17 Sep 2020 01:44:14

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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).		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: 11 Aug 2021 22:15:45**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered 'Oral (Oral)'		17 Sep 2020 01:45:38

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered empty.		17 Sep 2020 01:45:38

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '74'		17 Sep 2020 01:45:38

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User entered 'bpm'	System	17 Sep 2020 01:45:38



US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '18'		17 Sep 2020 01:45:38

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User entered 'breaths/min'	System	17 Sep 2020 01:45:38

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '119'		17 Sep 2020 01:45:38

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User entered 'mmHg'	System	17 Sep 2020 01:45:38

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:16
User entered '85'		17 Sep 2020 01:45:38

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09
User entered 'mmHg'	System	17 Sep 2020 01:45:38

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09

US3322061

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:09



**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:15:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:42
User entered 'Yes (Y)'		17 Sep 2020 01:46:43

**US3322061**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:15:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:29:42
User entered '11 Sep 2020'		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: 11 Aug 2021 22:15:45

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:30:02
User entered 'Yes (Y)'		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: 11 Aug 2021 22:15:45**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:30:02
User entered '11 Sep 2020'		17 Sep 2020 01:46:55

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:39
User entered 'Yes (Y)'		21 Oct 2020 13:19:32

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:39
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: 11 Aug 2021 22:15:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:39
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: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:46
User entered 'SICKD28'	System	21 Oct 2020 13:19:32



US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
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: 11 Aug 2021 22:15:45

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User entered 'bpm'	System	21 Oct 2020 13:21:19

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User entered 'breaths/min'	System	21 Oct 2020 13:21:19

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User entered 'mmHg'	System	21 Oct 2020 13:21:19

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:50:58
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: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50
User entered 'mmHg'	System	21 Oct 2020 13:21:19

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:50

US3322061

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:53:04
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: 11 Aug 2021 22:15:45

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:53:04
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: 11 Aug 2021 22:15:45

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:54:14
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).		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: 11 Aug 2021 22:15:45

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:37:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:54:14
User entered '14 Oct 2020'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 13:21:57

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:11



US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:11

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 22:34:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:22

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:15:45**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:09:38

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:09:38

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:22



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 02:56:05
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 02:56:05
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4) (b) (4)	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:15:45

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:34:22

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:15:45**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'I'	System	15 Jan 2021 22:34:22

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'I'	System	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20



US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	15 Jan 2021 22:35:20
DataPoint set to visible.	System	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	15 Jan 2021 22:35:20
DataPoint set to visible.	System	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15:05'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20



**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered '15 Jan 2021 15:05'	System	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '97.1' F	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '64'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'bpm'	System	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'breaths/min'	System	15 Jan 2021 22:35:20



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '120'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'mmHg'	System	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '84'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'mmHg'	System	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:15:45

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	15 Jan 2021 22:35:20
DataPoint set to visible.	System	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	15 Jan 2021 22:35:20



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '16:27'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered '15 Jan 2021 16:27'	System	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '96.9' F	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '62'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20



**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'bpm'	System	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'breaths/min'	System	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '128'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'mmHg'	System	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '81'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'mmHg'	System	15 Jan 2021 22:35:20

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:37



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:15:45

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:35:37

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	15 Jan 2021 22:36:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	15 Jan 2021 22:36:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'mRNA-1273'	System	15 Jan 2021 22:36:11
DataPoint set to visible.	System	15 Jan 2021 22:34:22

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15:48'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:11

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:15:45**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered '15 Jan 2021 15:48'	System	15 Jan 2021 22:36:11



US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'ONCE'	System	15 Jan 2021 22:36:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 22:36:11

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:28

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:28

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15:33'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:28

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:15:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered '15 Jan 2021 15:33'	System	15 Jan 2021 22:36:28

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:15:45

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:34



**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:15:45**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15 Jan 2021'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:34

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:15:45

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15:28'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:34

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:15:45**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered '15 Jan 2021 15:28'	System	15 Jan 2021 22:36:34

US3322061

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Jan 2021 22:36:38

**US3322061**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'I'	System	15 Jan 2021 22:36:38

**US3322061**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:02:51

**US3322061**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '22 Jan 2021'	Elisa Moralez (b) (4)	22 Jan 2021 19:02:51

**US3322061**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	22 Jan 2021 19:02:51



US3322061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	22 Jan 2021 19:02:51

**US3322061**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	22 Jan 2021 19:02:40

**US3322061**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'I'	System	22 Jan 2021 19:02:40

**US3322061**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'I'	System	22 Jan 2021 19:02:40
DataPoint set to visible.	System	22 Jan 2021 19:02:40

**US3322061**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Feb 2021 23:38:59

**US3322061**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11 Feb 2021'	Elisa Moralez (b) (4)	11 Feb 2021 23:38:59

**US3322061**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	11 Feb 2021 23:38:59

**US3322061**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'OLD29'	System	11 Feb 2021 23:38:59



US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11 Feb 2021'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '14:49'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered '11 Feb 2021 14:49'	System	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '98.0' F	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52



**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '54'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'bpm'	System	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'breaths/min'	System	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '118'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'mmHg'	System	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '71'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'mmHg'	System	11 Feb 2021 23:40:52



US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11 Feb 2021'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '16:24'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered '11 Feb 2021 16:24'	System	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '96.9' F	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	11 Feb 2021 23:40:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Feb 2021 23:40:57
User entered 'Oral (Oral)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	11 Feb 2021 23:40:57
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	11 Feb 2021 23:40:52
User entered empty.	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52
	(b) (4)	

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52



**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '51'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'bpm'	System	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'breaths/min'	System	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '135'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'mmHg'	System	11 Feb 2021 23:40:52

US3322061

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '84'	Elisa Moralez (b) (4)	11 Feb 2021 23:40:52

**US3322061**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'mmHg'	System	11 Feb 2021 23:40:52



**US3322061**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:15:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Feb 2021 23:41:04

**US3322061**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:15:45**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11 Feb 2021'	Elisa Moralez (b) (4)	11 Feb 2021 23:41:04

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'mRNA-1273'	System	11 Feb 2021 23:41:14
DataPoint set to visible.	System	22 Jan 2021 19:02:40

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '11 Feb 2021'	Elisa Moralez (b) (4)	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '15:45'	Elisa Moralez (b) (4)	11 Feb 2021 23:41:14



US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered '11 Feb 2021 15:45'	System	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4)	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'ONCE'	System	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:15:45

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 23:41:14

US3322061

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Feb 2021 23:41:17

**US3322061**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered 'I'	System	11 Feb 2021 23:41:17

**US3322061**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	02 Mar 2021 19:52:15

**US3322061**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered '20 Feb 2021'	Elisa Moralez (b) (4)	02 Mar 2021 19:52:15



**US3322061**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:15:45**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	02 Mar 2021 19:52:15

US3322061

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:15:45

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	02 Mar 2021 19:52:15

US3322061

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:15:45

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	02 Mar 2021 19:52:20

**US3322061**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:15:45**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'I'	System	02 Mar 2021 19:52:20

**US3322061**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:16

**US3322061**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered '12 Mar 2021'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:16

US3322061

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:15:45

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:16

**US3322061**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:15:45**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered 'OLD57'	System	12 Mar 2021 21:05:16



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**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

US3322061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	12 Mar 2021 21:05:21

US3322061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

US3322061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21



**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	12 Mar 2021 21:05:21

US3322061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	12 Mar 2021 21:05:21

US3322061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	12 Mar 2021 21:05:21

US3322061

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27
User entered empty.	System	12 Mar 2021 21:05:21

**US3322061**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:15:45**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27



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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:15:45

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:27:27

**US3322061**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:15:45**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'No (N)'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:26

**US3322061**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:15:45**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered empty.	Elisa Moralez (b) (4)	12 Mar 2021 21:05:26

**US3322061**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:15:45**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:39

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:15:45

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered '12 Mar 2021'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:39

**US3322061**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:15:45**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:52:41
User entered '13:25'	Elisa Moralez (b) (4)	12 Mar 2021 21:05:39

**US3322061**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:15:45**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:26:17
User entered '12 Mar 2021 13:25'	System	12 Mar 2021 21:05:39

**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:15:45**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:17
User entered 'Yes (Y)'		17 Sep 2020 01:29:18



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:15:45**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:51:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:51:52
Data point term sent to Coder	System	29 Sep 2020 18:31:42
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	29 Sep 2020 18:30:58
User entered 'Symptomatic Covid -19' reason for change: Data Entry Error	Frances Saubon (b) (4) (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, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	22 Sep 2020 20:58:57
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:58:51
User entered 'Covid-19' reason for change: Data Entry Error	Frances Saubon (b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	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) (b) (4)	17 Sep 2020 05:22:53
Data point term sent to Coder	System	17 Sep 2020 01:33:24
User entered 'Symptomatic confirmed positive COVID-19 case'	(b) (4), (b) (6) (b) (4)	17 Sep 2020 01:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'Yes (Y)'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'No (N)'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'Yes (Y)'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '07 Sep 2020'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty.		17 Sep 2020 01:32:39



**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'No (N)'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '15 Sep 2020'		17 Sep 2020 01:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty.		17 Sep 2020 01:32:39

**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'No (N)'		17 Sep 2020 01:32:39

**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '0'		17 Sep 2020 01:32:39



US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '0'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '0'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty.		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty.		17 Sep 2020 01:32:39

**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty.		17 Sep 2020 01:32:39

**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:15:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty.		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '0'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '0'		17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '0'		17 Sep 2020 01:32:39

US3322061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
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).		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) (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) (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: 11 Aug 2021 22:15:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'Not Related (NOT RELATED)'		17 Sep 2020 01:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
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).		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).		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)'		17 Sep 2020 01:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
Signature has been broken.	(b) (4)	
	Elisa Morales (b) (4)	05 Apr 2021 14:08:15
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
	(b) (4)	
Signature has been broken.	Moez Talpur (b) (4)	26 Mar 2021 20:48:52
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered '0'		17 Sep 2020 01:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
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).		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 'I'		17 Sep 2020 01:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
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).		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) (b) (4)	09 Oct 2020 21:13:58
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4) (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) (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: 11 Aug 2021 22:15:45**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		17 Sep 2020 01:32:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty.		17 Sep 2020 01:32:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:15:45

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:13
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 01:32:39

**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site lymphadenopathy, LLT: Injection site lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 10:05:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 10:05:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: Lymphadenopathy axillary - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 16:03:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 16:03:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site lymphadenopathy, LLT: Injection site lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 19:56:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 19:56:55
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)	10 Dec 2020 12:42:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 12:42:13
User closed 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)	02 Dec 2020 18:47:41
Data point term sent to Coder	System	01 Dec 2020 18:41:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Adverse event](#)

Audit	User	Time (GMT)
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.' answered with 'please see updated term' (Site from DM). Coding entries removed.	Frances Saubon (b) (4)	01 Dec 2020 18:40:41
User entered 'Ipsilateral injection site AXILLARY LYMPHADENOPATHY, LEFT AXILLA' reason for change: Per Query Resolution	Frances Saubon (b) (4)	01 Dec 2020 18:40:31
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)	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)	11 Nov 2020 03:37:50

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (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) (4), (b) (6)	10 Nov 2020 19:22:45
Data point term sent to Coder	System	09 Nov 2020 20:16:27
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).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:16:04
Coding entries removed.	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:15:43
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).		01 Nov 2020 00:12:47



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Adverse event](#)

Audit	User	Time (GMT)
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) (b) (4)	30 Oct 2020 21:14:04
Data point term sent to Coder	System	30 Oct 2020 20:56:08
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).	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 20:56:04
Coding entries removed.	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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Adverse event](#)

Audit	User	Time (GMT)
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: 11 Aug 2021 22:15:45

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '27 Aug 2020'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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 (b) (4)	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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User entered empty.	System	29 Sep 2020 18:32:20
User entered '27 Aug 2020 00:00'	System	25 Sep 2020 14:33:44



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '28 Aug 2020'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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 (b) (4)	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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User entered empty.	System	29 Sep 2020 18:32:20
User entered '28 Aug 2020 00:00'	System	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'None (NONE)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'I'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:33:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User entered '0'	System	25 Sep 2020 14:33:44

**US3322061**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:15:45**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48
User entered '0'	System	25 Sep 2020 14:33:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:15:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:27:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:15:45

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:19:25
User closed query 'Per ETRTR: Please confirm medication dosed for Indication COVID-19, thanks.' (Site from CRA).		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) (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), (b) (6)	23 Sep 2020 00:14:00
User entered 'Yes (Y)'		17 Sep 2020 01:34:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:15:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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.	(b) (4) 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:15:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 22:15:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Hot Flashes'	(b) (4) (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: 11 Aug 2021 22:15:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
Signature has been broken.	Moez Talpur (b) (4)	26 Mar 2021 20:49:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '37.5'	(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: 11 Aug 2021 22:15:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'mg (mg)'	(b) (4) (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: 11 Aug 2021 22:15:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) (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: 11 Aug 2021 22:15:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'once daily (QD)'	(b) (4) (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: 11 Aug 2021 22:15:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:44:57
Signature has been broken.	(b) (4)	
	Moez Talpur (b) (4)	26 Mar 2021 20:49:21
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
	(b) (4)	
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: 11 Aug 2021 22:15:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Oral (ORAL)'	(b) (4) (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: 11 Aug 2021 22:15:45**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) (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: 11 Aug 2021 22:15:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN Jun 2020' reason for change: Data Entry Error	System	17 Sep 2020 01:37:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 01:37:03
User entered '00 Jun 2020' (non-conformant).		
	(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: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	(b) (4) (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: 11 Aug 2021 22:15:45**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 22:15:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '03 Sep 2020'	(b) (4) (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: 11 Aug 2021 22:15:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 22:15:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
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: 11 Aug 2021 22:15:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
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: 11 Aug 2021 22:15:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:14
User entered '804 (804)'	System	17 Sep 2020 01:36:45

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:45

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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)	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)	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)	17 Sep 2020 01:39:15



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:15:45

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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) (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: 11 Aug 2021 22:15:45

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Supplements'	(b) (4) (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: 11 Aug 2021 22:15:45**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'I'	(b) (4) (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: 11 Aug 2021 22:15:45

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
Data Entry Error	Frances Saubon (b) (4)	22 Sep 2020 20:57:32
User entered 'Other (OTHER)'	(b) (4)	
	(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: 11 Aug 2021 22:15:45

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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) (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) (b) (4)	22 Sep 2020 20:57:39
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'once daily (QD)'	(b) (4) (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: 11 Aug 2021 22:15:45**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) (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: 11 Aug 2021 22:15:45**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Oral (ORAL)'	(b) (4) (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: 11 Aug 2021 22:15:45**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) (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: 11 Aug 2021 22:15:45**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'UN Jan 2010'	(b) (4) (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: 11 Aug 2021 22:15:45**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '0'	(b) (4) (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: 11 Aug 2021 22:15:45**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'Yes (Y)'	(b) (4) (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: 11 Aug 2021 22:15:45**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	(b) (4) (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: 11 Aug 2021 22:15:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	(b) (4) (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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45**

[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: 11 Aug 2021 22:15:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
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) (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) (b) (4)	09 Nov 2020 15:49:33
Data point term sent to Coder	System	09 Nov 2020 15:48:44
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 15:48:25
User entered 'Acetaminophen' reason for change: Data Entry Error	Frances Saubon (b) (4) (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) (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) (b) (4)	22 Oct 2020 19:25:29
Data point term sent to Coder	System	22 Oct 2020 18:59:51
Coding entries removed.	Elisa Moralez (b) (4) (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) (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) (b) (4)	17 Sep 2020 01:42:48
Data point term sent to Coder	System	17 Sep 2020 01:41:27

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Tylenol'	(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: 11 Aug 2021 22:15:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered 'No (N)'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
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).		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) (b) (4)	22 Oct 2020 18:59:26
User entered 'symptomatic covid-19' reason for change: New Information	Elisa Moralez (b) (4) (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'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered '500'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
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).		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) (b) (4)	22 Oct 2020 18:59:46
User entered 'mg (mg)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (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)'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered empty.		17 Sep 2020 01:40:59



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered 'as needed (PRN)'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered empty.		17 Sep 2020 01:40:59

**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:15:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered 'Oral (ORAL)'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered empty.		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered '07 Sep 2020'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
User entered '0'		17 Sep 2020 01:40:59

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:15:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
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).		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) (b) (4)	09 Nov 2020 15:48:45
User entered 'No (N)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:20:50
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: 11 Aug 2021 22:15:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 19:20:50
User entered 'No (N)'		17 Sep 2020 01:40:59

US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:15:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
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: 11 Aug 2021 22:15:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
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: 11 Aug 2021 22:15:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:10
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: 11 Aug 2021 22:15:45

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE 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	System	22 Oct 2020 18:59:52
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	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;PHE NYLEPHRINE - 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	System	17 Sep 2020 01:42:28
User entered 'Theraflu (Acetaminophen, Dextromethorphan,Phenylephrine HCL)'	(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: 11 Aug 2021 22:15:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered 'No (N)'		17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
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).		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) (b) (4)	22 Oct 2020 18:59:00
User entered 'symptomatic covid-19' reason for change: New Information	Elisa Moralez (b) (4) (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'		17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered 'l'		17 Sep 2020 01:42:14



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered 'Other (OTHER)'		17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered 'TEA BAG'		17 Sep 2020 01:42:14

**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:15:45**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered 'as needed (PRN)'		17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered empty.		17 Sep 2020 01:42:14

**US3322061**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:15:45**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered 'Oral (ORAL)'		17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered empty.		17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered '10 Sep 2020'		17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered '0'		17 Sep 2020 01:42:14



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:15:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
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).		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) (b) (4)	09 Nov 2020 16:03:20
User entered 'No (N)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (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: 11 Aug 2021 22:15:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
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: 11 Aug 2021 22:15:45**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:30
User entered 'No (N)'		17 Sep 2020 01:42:14

US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:15:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
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: 11 Aug 2021 22:15:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
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: 11 Aug 2021 22:15:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:29:15
User entered empty.	System	17 Sep 2020 01:42:14

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 15:53:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 15:53:51
Data point term sent to Coder	System	09 Apr 2021 15:44:55
User entered 'Influenza vaccine'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'Prophylaxis'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'I'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'Other (OTHER)'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'injection'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'once (ONCE)'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered empty.	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'Intramuscular (INTRAMUSCULAR)'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered empty.	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35



US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'un Sep 2020'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered '0'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'un Sep 2020'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:15:45

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:25:58
User entered 'No (N)'	Elisa Moralez (b) (4)	09 Apr 2021 15:44:35

US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:15:45**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User entered empty.	System	09 Apr 2021 15:44:35

US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:15:45**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User entered empty.	System	09 Apr 2021 15:44:35

US3322061

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:15:45**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:10:20
User entered empty.	System	09 Apr 2021 15:44:35



US3322061

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:15:45**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:49:35

**US3322061**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:15:45**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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).		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: 11 Aug 2021 22:15:45

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (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: 11 Aug 2021 22:15:45

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (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) (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) (b) (4)	25 Sep 2020 14:45:53
User entered '16 Sep 2020'	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: 11 Aug 2021 22:15:45

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (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) (b) (4)	25 Sep 2020 14:46:58
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) (b) (4)	25 Sep 2020 14:45:53
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	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: 11 Aug 2021 22:15:45

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
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: 11 Aug 2021 22:15:45

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:35:40



US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:15:45

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:35:40

US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:15:45

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:35:40

US3322061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:15:45

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:49
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered empty.	Elisa Moralez (b) (4)	25 Sep 2020 14:35:40

**US3322061**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:15:45**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '2'	(b) (4)	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: 11 Aug 2021 22:15:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '2'	(b) (4)	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: 11 Aug 2021 22:15:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
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: 11 Aug 2021 22:15:45

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		23 Sep 2020 18:01:49
User entered 'I'		17 Sep 2020 15:55:54

US3322061

Folder: SAE USA-US060-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:15:45

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
Reviewed for Safety.		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: 11 Aug 2021 22:15:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
User entered '2'	(b) (4)	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: 11 Aug 2021 22:15:45**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
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: 11 Aug 2021 22:15:45

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 02:09:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:16
User entered 'I'		23 Sep 2020 18:02:00