

US3682211 (Prod: UCLA Vine Street Clinic - (CRS))

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:05:54

All time stamps listed in this document are displayed in GMT

US3682211

Form: Participant Creation

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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[Participant ID](#)

US3682211

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

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US3682211

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	True
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) 19 Feb 2021 23:24:16

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	23 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 23:24:16

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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) 19 Feb 2021 23:24:16

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Condition	DYSLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Condition	POST MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:15
Height (xxx.x)	62 in
Weight (xxx.x)	110 lb
BMI (xxx.x)	20.16133 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 23:24:16

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Date of assessment (*dd MMM yyyy*) 23 OCT 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*) 01 DEC 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:24:16

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 23:24:16

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<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)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

What was the date of randomization? (dd MMM yyyy) 23 OCT 2020

What was the participant's randomization number? 117684

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) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

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) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

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)	23 OCT 2020
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:15
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:00
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

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) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 09:18 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 09:18

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) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

09:04 (24 HR)

Collection date and time (derived)

23 OCT 2020 09:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:36:28

Generated On: 11 Aug 2021 23:05:54

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:09	23 OCT 2020 09:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:36:28

Generated On: 11 Aug 2021 23:05:54

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 23:05:54

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 10:12

PC Open Date & Time

23 OCT 2020 09:38

PC Close Date & Time

23 OCT 2020 12:08

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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	23 OCT 2020 17:29
PC Open Date & Time	23 OCT 2020 13:03
PC Close Date & Time	24 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**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

97.8 °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

24 OCT 2020 13:15

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**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

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

25 OCT 2020 21:35

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 02:02

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 12:14

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 OCT 2020 12:55

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 12:10

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

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

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 OCT 2020 10:12

PC Open Date & Time

23 OCT 2020 09:38

PC Close Date & Time

23 OCT 2020 12:08

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**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

23 OCT 2020 17:29

PC Open Date & Time

23 OCT 2020 13:03

PC Close Date & Time

24 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**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

24 OCT 2020 13:16

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**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

25 OCT 2020 21:36

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**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

27 OCT 2020 02:03

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**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

27 OCT 2020 12:14

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**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

28 OCT 2020 12:55

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**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

29 OCT 2020 12:11

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59



US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**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 ☐

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 10:14
PC Open Date & Time	23 OCT 2020 09:38
PC Close Date & Time	23 OCT 2020 12:08

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**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 ☐

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 17:30
PC Open Date & Time	23 OCT 2020 13:03
PC Close Date & Time	24 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 13:17
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 ☐

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

Yes ☐

PC Time stamp

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59



US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 ☒

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 02:04
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 ☒

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 12:15
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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 ☒

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EAB) (1725)

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 12:56
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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 ☒

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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



US3682211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:36:32

Generated On: 11 Aug 2021 23:05:54

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)	20 NOV 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	20 NOV 2020 12:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG



US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:36:32

Generated On: 11 Aug 2021 23:05:54

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)	20 NOV 2020
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	20 NOV 2020 13:46
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	51 mmHg
Diastolic Blood Pressure units	MMHG

US3682211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 NOV 2020

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

US3682211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

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) 20 NOV 2020

What was the treatment time? (00:00-23:59) 13:12 (24 HR)

Treatment Date and Time (derived) 20 NOV 2020 13:12

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

US3682211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 NOV 2020

Collection time (00:00-23:59)

13:02 (24 HR)

Collection date and time (derived)

20 NOV 2020 13:02

US3682211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Collection date (dd MMM yyyy)			20 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:04	20 NOV 2020 13:04
Nasopharyngeal Swab 2	No		

US3682211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:36:31

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

20 NOV 2020 16:02

PC Open Date & Time

20 NOV 2020 13:32

PC Close Date & Time

20 NOV 2020 16:02

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	20 NOV 2020 20:07
PC Open Date & Time	20 NOV 2020 16:57
PC Close Date & Time	21 NOV 2020 11:59



US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

22 NOV 2020 12:21

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 22:14

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 NOV 2020 12:12

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

26 NOV 2020 01:48

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PC Open Date & Time

25 NOV 2020 12:00

---

PC Close Date & Time

26 NOV 2020 11:59

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US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 NOV 2020 04:11

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 NOV 2020 13:32

PC Close Date & Time

20 NOV 2020 16:02

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**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

20 NOV 2020 20:08

PC Open Date & Time

20 NOV 2020 16:57

PC Close Date & Time

21 NOV 2020 11:59



US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

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

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**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

22 NOV 2020 12:21

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**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

23 NOV 2020 22:14

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**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

24 NOV 2020 12:12

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**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 NOV 2020 01:48

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**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 NOV 2020 04:11

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**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 ☐

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 NOV 2020 13:32

PC Close Date & Time

20 NOV 2020 16:02



US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**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 ☐

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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

No ☒

Yes ☐

PC Time stamp	20 NOV 2020 20:08
PC Open Date & Time	20 NOV 2020 16:57
PC Close Date & Time	21 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**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 ☐

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EAB) (1725)

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US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Yes ☐

PC Time stamp

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 ☒

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 12:21
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 ☒

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EAB) (1725)

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 22:14
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59



US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 ☒

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EAB) (1725)

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**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 ☒

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	26 NOV 2020 01:48
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

Yes <input type="checkbox"/>	
PC Time stamp	27 NOV 2020 04:11
PC Open Date & Time	26 NOV 2020 12:00
PC Close Date & Time	27 NOV 2020 11:59

US3682211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:24:16

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3682211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:36:28

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:36:28

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:36:28

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:36:28

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:36:32

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 19:36:32

Generated On: 11 Aug 2021 23:05:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	15:01 (24 HR)
Vital Signs Date and Time (derived)	23 DEC 2020 15:01
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	79 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:36:32

Generated On: 11 Aug 2021 23:05:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 DEC 2020

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

US3682211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 19:36:32

Generated On: 11 Aug 2021 23:05:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 DEC 2020

Collection time (00:00-23:59)

15:11 (24 HR)

Collection date and time (derived)

23 DEC 2020 15:11



US3682211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:36:32

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 DEC 2020 15:34:41
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 68

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

No ☒

Yes ☐

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

27 DEC 2020 15:23:53

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	04 JAN 2021 02:52:42
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	10 JAN 2021 04:17:39
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 JAN 2021 12:35:46
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 JAN 2021 22:44:54
Patient Cloud Open Date & Time	24 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
118 of 2252	

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 13:14:26

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 FEB 2021 15:29:39
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 02:24:20

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 17:01:00

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 14:11:01

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 14:53:37

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

Date and time of submission

18 MAR 2021 18:12:07

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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

21 MAR 2021 20:38:27

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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

31 MAR 2021 23:23:15

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 19:43:12

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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

12 APR 2021 15:34:11

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 01:21:43

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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

25 APR 2021 12:02:27

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 09:54:32

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	_____
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Close Date & Time](#)

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19 AUG 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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°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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 <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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 <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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 <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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 MAR 2022 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 516

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

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20 MAR 2022 00:01

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24 MAR 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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27 MAR 2022 00:01

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31 MAR 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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07 APR 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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24 APR 2022 00:01

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28 APR 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 <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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

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11 AUG 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 ☐

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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08 SEP 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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11 SEP 2022 00:01

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15 SEP 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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18 SEP 2022 00:01

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22 SEP 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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06 OCT 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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



US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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°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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

13 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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27 NOV 2022 00:01

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01 DEC 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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 <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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2022 23:59

US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2022 23:59

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US3682211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:05:54

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

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2022 23:59
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**US3682211**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 23:05:54**

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		02 MAR 2021 14:11:16

US3682211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:19:10

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:10

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3682211

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 18:42:53

Generated On: 11 Aug 2021 23:05:54

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*

US3682211

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 18:42:53

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3682211**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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 \_\_\_\_\_

US3682211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

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)	

US3682211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:54

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.*

**US3682211**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

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)	_____

**US3682211**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

Date of Contact	25 JAN 2021
Time of Contact	12:40
Date and Time of Contact (derived)	25 JAN 2021 12:40
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>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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"/>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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"/>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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"/>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 ☐

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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"/>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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"/>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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"/>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

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Form: Symptom Log (4)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (4)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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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 (5)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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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 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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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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

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Form: Symptom Log (5)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (5)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input 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 (6)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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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 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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (6)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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

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Form: Symptom Log (7)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 (7)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Data signed: (b) (4) 01 Apr 2021 21:05:23

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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 (8)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 (8)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (8)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input 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 25 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	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	25 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input 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 25 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 (10)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (10)

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Generated On: 11 Aug 2021 23:05:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (10)

Data signed: (b) (4) 01 Apr 2021 21:05:23

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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 (11)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 (11)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (11)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

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Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 (12)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Generated On: 11 Aug 2021 23:05:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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Form: Symptom Log (12)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 ☐

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 (13)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 25 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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 ☐

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

Symptom Day

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

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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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EAB) (1725)

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US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

Symptom Day

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

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 25 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 25 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 25 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

	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"/>



US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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"/>

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

Date of Visit	29 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	29 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3682211

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	31 JAN 2021
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3682211

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3682211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JAN 2021
Time of assessment (00:00-23:59)	16:10 (24 HR)
Vital Signs Date and Time (derived)	29 JAN 2021 16:10
Height (xxx.x)	62 in
Weight (xxx.x)	110 lb
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682211

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

29 JAN 2021

---

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

---

US3682211

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

29 JAN 2021

**US3682211**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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 \_\_\_\_\_



US3682211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

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)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:54

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: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3682211

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

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 JAN 2021
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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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Date of updated informed consent ( <i>dd MMM yyyy</i> )	11 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> )	11 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

US3682211

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3682211

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

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)	13:15 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 13:15
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	39 mmHg
Diastolic Blood Pressure units	MMHG

US3682211

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

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)	14:01 (24 HR)
Vital Signs Date and Time (derived)	15 JAN 2021 14:01
Temperature (xxx.x)	98.4 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG



US3682211

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

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

11 JAN 2021

---

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

---

US3682211

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

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

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) 13:29 (24 HR)

Treatment Date and Time (derived) 15 JAN 2021 13:29

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

US3682211

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00-23:59)	16:36 (24 HR)
Collection date and time (derived)	11 JAN 2021 16:36

US3682211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

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

Collection date (dd MMM yyyy)	11 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	16:41
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Collection Date and Time (derived)	11 JAN 2021 16:41
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US3682211

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

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 21:05:24

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:19:10

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:19:10

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3682211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

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)	26 FEB 2021
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 16:35
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3682211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3682211

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

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 PT. REFUSED SECOND DOSE

What was the study treatment? (Unblinded) \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3682211

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3682211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:34:16

Generated On: 11 Aug 2021 23:05:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3682211

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 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



US3682211

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	8 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	12:50 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 12:50
Temperature ( <i>xxx.x</i> )	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	73 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3682211

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 APR 2021

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

US3682211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 APR 2021
Collection time (00:00-23:59)	13:06 (24 HR)
Collection date and time (derived)	8 APR 2021 13:06

US3682211

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 21:21:01

Generated On: 11 Aug 2021 23:05:54

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3682211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

AEID	
Adverse event	INTERMITTENT HEADACHE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 JAN 2021
Start time (00:00-23:59)	18:00 (24 HR)
AE start date and time (derived)	16 JAN 2021 18:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

---

PT PREVIOUSLY EVALUATED  
FOR ILLNESS SYMPTOMS,  
INCLUDING HEADACHE.  
HEADACHE REPORTED AS  
CONTINUED AND  
INTERMITTENT. PT DENIED USE  
OF MEDICATION AND SAID  
THAT THE HEADACHES  
SELF-RESOLVE IN 30 MINUTES  
TO AN HOUR.

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
------------------------------------------------------------	---

Medically Attended AE Derived (CSA Programming Field Only)	1
------------------------------------------------------------	---

---

Admitted to ICU Derived (CSA Programming Field Only)	
------------------------------------------------------	--

---

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US3682211

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

AEID	
Adverse event	COVID-LIKE ILLNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3682211

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

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

US3682211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

---

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

Yes ☐

No ☒

---

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

---

US3682211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 01 Apr 2021 21:05:23

Generated On: 11 Aug 2021 23:05:54

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3682211

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Apr 2021 21:28:57

Generated On: 11 Aug 2021 23:05:54

---

Date of dosing discontinuation (dd MMM yyyy)

---

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

---

US3682211

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:05:54

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 ☐

Audit

US3682211 (Prod: UCLA Vine Street Clinic - (CRS))

**US3682211**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 23:05:54**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'US3682211'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:33:38

**US3682211**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:03



US3682211

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:33:39

US3682211

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:03

**US3682211**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'SCRN'	System	23 Oct 2020 15:34:03

US3682211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered (b) (6) 1963'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:33:41

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '56'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'YEARS'	System	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered '56'	System	23 Oct 2020 15:34:18

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Female (F)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14



US3682211

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:05:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'I'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14



**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:05:54**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:32:14

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:18

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'Oct 2020'	System	23 Oct 2020 15:34:18

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered '2020'	System	23 Oct 2020 15:34:18

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:18

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:18

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:18



**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:18

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:18

US3682211

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 23:05:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:33:39

**US3682211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:05:54**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'I'	System	23 Oct 2020 15:34:22

**US3682211**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:22

**US3682211**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 23:05:54**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:34:34

US3682211

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:05:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Dyslipidaemia, LLT: Dyslipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:37:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 15:37:31
Data point term sent to Coder	System	23 Oct 2020 15:36:07
User entered 'DYSLIPIDEMIA'	(b) (4), (b) (6)	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'UN UNK 2020'	(b) (4), (b) (6)	23 Oct 2020 15:35:09



**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'Jan 2020'	System	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered '2020'	System	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered empty.	System	23 Oct 2020 15:35:09

**US3682211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered empty.	System	23 Oct 2020 15:35:09



US3682211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:12:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:12:44
Data point term sent to Coder	System	18 Dec 2020 19:11:31
User entered 'Post Menopause'	Susan Reed (b) (4)	18 Dec 2020 19:10:41

**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'un UNK 2015'	(b) (4) Susan Reed (b) (4) (b) (4)	18 Dec 2020 19:10:41

US3682211

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:05:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	Susan Reed (b) (4)	18 Dec 2020 19:10:41

**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	18 Dec 2020 19:10:41

**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	Susan Reed (b) (4)	18 Dec 2020 19:10:41

**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:41
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	Susan Reed (b) (4)	18 Dec 2020 19:10:41

**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'Jan 2015'	System	18 Dec 2020 19:10:41

**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered '2015'	System	18 Dec 2020 19:10:41



**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered empty.	System	18 Dec 2020 19:10:41

**US3682211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered empty.	System	18 Dec 2020 19:10:41

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '23 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '08:15'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered '23 Oct 2020 08:15'	System	23 Oct 2020 16:33:16

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '62' in	(b) (4)	
	Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16
DataPoint set to visible.	(b) (4)	
	System	23 Oct 2020 15:34:22

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '110' lb	(b) (4)	
	Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16
DataPoint set to visible.	(b) (4)	
	System	23 Oct 2020 15:34:22



**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered '20.16133'	System	23 Oct 2020 16:33:16
DataPoint set to visible.	System	23 Oct 2020 15:34:22

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'kg/m2'	System	23 Oct 2020 16:33:16
DataPoint set to visible.	System	23 Oct 2020 15:34:22

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered missing code ND - Not Done.	Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'bpm'	System	23 Oct 2020 16:33:16

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16



**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'breaths/min'	System	23 Oct 2020 16:33:16

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'mmHg'	System	23 Oct 2020 16:33:16

US3682211

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:33:16

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User entered 'mmHg'	System	23 Oct 2020 16:33:16

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14

**US3682211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14

**US3682211**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:20



**US3682211**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:20

**US3682211**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:05:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '23 Oct 2020'	Schuyler Thomas (b) (4)	23 Oct 2020 16:34:27

US3682211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:54

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:34:27

US3682211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:54

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
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)	22 Dec 2020 04:49:59
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 'added to medical hx' (Site from DM).	Susan Reed (b) (4) (b) (4)	18 Dec 2020 19:10:10
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)	18 Dec 2020 16:51:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Schuyler Thomas (b) (4) (b) (4)	23 Oct 2020 16:34:27

**US3682211**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:05:54**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:34:27

US3682211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	Schuyler Thomas (b) (4)	23 Oct 2020 16:34:27

**US3682211**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:05:54**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:34:27

US3682211

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 23:05:54

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '01 Dec 2015'	Schuyler Thomas (b) (4)	23 Oct 2020 16:34:27



**US3682211**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:05:54**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	Schuyler Thomas (b) (4)	23 Oct 2020 16:34:27

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

[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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41



US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

[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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

**US3682211**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:05:54**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41



US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

[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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

**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)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

US3682211

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

**US3682211**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:05:54**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

**US3682211**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:48:14
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:35:41

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:34:43

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:34:43



**US3682211**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Clinic (Clinic)'	Schuyler Thomas (b) (4)	23 Oct 2020 16:34:43

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'VISIT1'	System	23 Oct 2020 16:34:43

US3682211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:48:45

US3682211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '117684'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:48:45

US3682211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 15:48:45

US3682211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:54

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)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:14

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:05:54**

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)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	Schuyler Thomas (b) (4)	23 Oct 2020 16:36:14

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:14



**US3682211**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:14

US3682211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:05:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	Schuyler Thomas (b) (4)	23 Oct 2020 16:36:14

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:14
DataPoint set to visible.	(b) (4) System	23 Oct 2020 15:34:18

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Pre-Dose (PREDOSE)'	Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08



US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '08:15'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '23 Oct 2020 08:15'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '98.0' F	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '77'	Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08



**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'bpm'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '16'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'breaths/min'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '112'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '68'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08



US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:05:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered missing code ND - Not Done.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Post-Dose (POSTDOSE)'	Schuyler Thomas (b) (4) (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '10:00'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '23 Oct 2020 10:00'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '97.4' F	Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08



**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '70'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'bpm'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '16'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'breaths/min'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '108'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '66'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 17:33:08



**US3682211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	23 Oct 2020 17:33:08

US3682211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:24

US3682211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:24

US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:44

US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:44

US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	Schuyler Thomas (b) (4)	23 Oct 2020 16:36:44

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'MRNA-1273 OR PLACEBO'	System	23 Oct 2020 16:36:44

US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Oct 2020'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:44



US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '09:18'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:44

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '23 Oct 2020 09:18'	System	23 Oct 2020 16:36:44

US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Right Arm (RIGHT ARM)'	Schuyler Thomas (b) (4)	23 Oct 2020 16:36:44

US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'ONCE'	System	23 Oct 2020 16:36:44

US3682211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'INTRAMUSCULAR'	System	23 Oct 2020 16:36:44

US3682211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:12

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:12

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '09:04'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:12



**US3682211**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '23 Oct 2020 09:04'	System	23 Oct 2020 20:09:12

US3682211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:05:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:37

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Oct 2020 20:09:37

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:37

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered '09:09'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:37

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '23 Oct 2020 09:09'	System	23 Oct 2020 20:09:37

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Oct 2020 20:09:37

US3682211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:05:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:37



**US3682211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:05:54**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:09:37

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered empty.	System	23 Oct 2020 20:09:37

US3682211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:05:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Oct 2020 16:36:52

**US3682211**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '1'	System	23 Oct 2020 16:36:52

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:11:40', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c36cf461-64a5-45ac-bb0b-35b1a9875e96'	System	23 Oct 2020 17:12:15
User entered 'Yes (Y)'	System	23 Oct 2020 17:12:15

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:11:55', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c36cf461-64a5-45ac-bb0b-35b1a9875e96' User entered '97.4'	System	23 Oct 2020 17:12:15
	System	23 Oct 2020 17:12:15

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:11:59', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c36cf461-64a5-45ac-bb0b-35b1a9875e96'	System	23 Oct 2020 17:12:15
User entered 'No (N)'	System	23 Oct 2020 17:12:15



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:12:11', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c36cf461-64a5-45ac-bb0b-35b1a9875e96'	System	23 Oct 2020 17:12:15
User entered '23 Oct 2020 10:12'	System	23 Oct 2020 17:12:15

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 09:38'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 12:08'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:28:57', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd3d69b73-69e2-4571-bfa6-59485615444c' User entered 'Yes (Y)'	System	24 Oct 2020 00:29:19
	System	24 Oct 2020 00:29:19

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:08', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd3d69b73-69e2-4571-bfa6-59485615444c' User entered '98.0'	System	24 Oct 2020 00:29:19
	System	24 Oct 2020 00:29:19

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:12', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd3d69b73-69e2-4571-bfa6-59485615444c' User entered 'No (N)'	System	24 Oct 2020 00:29:19
	System	24 Oct 2020 00:29:19

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:17', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd3d69b73-69e2-4571-bfa6-59485615444c' User entered '23 Oct 2020 17:29'	System	24 Oct 2020 00:29:19
	System	24 Oct 2020 00:29:19



US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 13:03'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 2'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:15:38', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2ea2f10e-2fe0-4479-8e17-87db153d9ce2' User entered 'Yes (Y)'	System	24 Oct 2020 20:16:07
	System	24 Oct 2020 20:16:07

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:15:48', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2ea2f10e-2fe0-4479-8e17-87db153d9ce2' User entered '97.8'	System	24 Oct 2020 20:16:07
	System	24 Oct 2020 20:16:07

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:15:54', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2ea2f10e-2fe0-4479-8e17-87db153d9ce2'	System	24 Oct 2020 20:16:07
User entered 'No (N)'	System	24 Oct 2020 20:16:07

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:15:59', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2ea2f10e-2fe0-4479-8e17-87db153d9ce2' User entered '24 Oct 2020 13:15'	System	24 Oct 2020 20:16:07
	System	24 Oct 2020 20:16:07

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 16:36:44



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 3'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:35:41', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '389c3319-38db-482c-aca8-e48e24e2c4fa' User entered 'Yes (Y)'	System	26 Oct 2020 04:35:55
	System	26 Oct 2020 04:35:55

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:35:47', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '389c3319-38db-482c-aca8-e48e24e2c4fa' User entered '96.5'	System	26 Oct 2020 04:35:55
	System	26 Oct 2020 04:35:55

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:35:50', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '389c3319-38db-482c-aca8-e48e24e2c4fa' User entered 'No (N)'	System	26 Oct 2020 04:35:55
	System	26 Oct 2020 04:35:55

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:35:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '389c3319-38db-482c-aca8-e48e24e2c4fa' User entered '25 Oct 2020 21:35'	System	26 Oct 2020 04:35:55
	System	26 Oct 2020 04:35:55

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:36:44



US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 4'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:02:13', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '01000c13-33f5-4c0d-8500-0c486f1a1d0f' User entered 'Yes (Y)'	System	27 Oct 2020 09:02:31
	System	27 Oct 2020 09:02:31

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:02:18', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '01000c13-33f5-4c0d-8500-0c486f1a1d0f' User entered '96.4'	System	27 Oct 2020 09:02:31
	System	27 Oct 2020 09:02:31

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:02:21', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '01000c13-33f5-4c0d-8500-0c486f1a1d0f' User entered 'No (N)'	System	27 Oct 2020 09:02:31
	System	27 Oct 2020 09:02:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:02:26', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '01000c13-33f5-4c0d-8500-0c486f1a1d0f' User entered '27 Oct 2020 02:02'	System	27 Oct 2020 09:02:31
	System	27 Oct 2020 09:02:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 5'	System	23 Oct 2020 16:36:44



US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:05', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c1891816-03d0-4f4d-97bf-9da11e8cfbfd'	System	27 Oct 2020 19:14:25
User entered 'Yes (Y)'	System	27 Oct 2020 19:14:25

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:17', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c1891816-03d0-4f4d-97bf-9da11e8cfbfd' User entered '97.9'	System	27 Oct 2020 19:14:25
	System	27 Oct 2020 19:14:25

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:20', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c1891816-03d0-4f4d-97bf-9da11e8cfbfd'	System	27 Oct 2020 19:14:25
User entered 'No (N)'	System	27 Oct 2020 19:14:25

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:23', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c1891816-03d0-4f4d-97bf-9da11e8cfbfd'	System	27 Oct 2020 19:14:25
User entered '27 Oct 2020 12:14'	System	27 Oct 2020 19:14:25

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 6'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:10', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '377479b2-42b6-4493-a136-4ee2835b3157'	System	28 Oct 2020 19:55:27
User entered 'Yes (Y)'	System	28 Oct 2020 19:55:27



US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:19', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '377479b2-42b6-4493-a136-4ee2835b3157' User entered '98.0'	System	28 Oct 2020 19:55:27
	System	28 Oct 2020 19:55:27

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:22', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '377479b2-42b6-4493-a136-4ee2835b3157'	System	28 Oct 2020 19:55:27
User entered 'No (N)'	System	28 Oct 2020 19:55:27

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:24', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '377479b2-42b6-4493-a136-4ee2835b3157' User entered '28 Oct 2020 12:55'	System	28 Oct 2020 19:55:27
	System	28 Oct 2020 19:55:27

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 7'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:10:26', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'aadabf99-a388-4ab6-81b0-80ae550db3a9' User entered 'Yes (Y)'	System	29 Oct 2020 19:10:53
	System	29 Oct 2020 19:10:53

US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:10:36', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'aadabf99-a388-4ab6-81b0-80ae550db3a9' User entered '98.0'	System	29 Oct 2020 19:10:53
	System	29 Oct 2020 19:10:53



US3682211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:10:42', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'aadabf99-a388-4ab6-81b0-80ae550db3a9'	System	29 Oct 2020 19:10:53
User entered 'No (N)'	System	29 Oct 2020 19:10:53

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:10:51', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'aadabf99-a388-4ab6-81b0-80ae550db3a9' User entered '29 Oct 2020 12:10'	System	29 Oct 2020 19:10:53
	System	29 Oct 2020 19:10:53

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:12:35', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '810dbb1a-d530-4a3a-9e8f-3bec6f6739bb' User entered 'None (1)'	System	23 Oct 2020 17:13:05
	System	23 Oct 2020 17:13:05

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:12:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '810dbb1a-d530-4a3a-9e8f-3bec6f6739bb' User entered 'No (N)'	System	23 Oct 2020 17:13:05
	System	23 Oct 2020 17:13:05

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:12:43', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '810dbb1a-d530-4a3a-9e8f-3bec6f6739bb' User entered 'No (N)'	System	23 Oct 2020 17:13:05
	System	23 Oct 2020 17:13:05



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:12:54', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '810dbb1a-d530-4a3a-9e8f-3bec6f6739bb'	System	23 Oct 2020 17:13:05
User entered 'None (1)'	System	23 Oct 2020 17:13:05

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:12:59', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '810dbb1a-d530-4a3a-9e8f-3bec6f6739bb' User entered '23 Oct 2020 10:12'	System	23 Oct 2020 17:13:05
	System	23 Oct 2020 17:13:05

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 09:38'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 12:08'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:24', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'e966b771-8af5-4b11-aec1-b65133ef38b6'	System	24 Oct 2020 00:29:42
User entered 'None (1)'	System	24 Oct 2020 00:29:42

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:28', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'e966b771-8af5-4b11-aec1-b65133ef38b6'	System	24 Oct 2020 00:29:42
User entered 'No (N)'	System	24 Oct 2020 00:29:42

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:32', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'e966b771-8af5-4b11-aec1-b65133ef38b6'	System	24 Oct 2020 00:29:42
User entered 'No (N)'	System	24 Oct 2020 00:29:42



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:36', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'e966b771-8af5-4b11-aec1-b65133ef38b6'	System	24 Oct 2020 00:29:42
User entered 'None (1)'	System	24 Oct 2020 00:29:42

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'e966b771-8af5-4b11-aec1-b65133ef38b6'	System	24 Oct 2020 00:29:42
User entered '23 Oct 2020 17:29'	System	24 Oct 2020 00:29:42

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 13:03'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 2'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:16:38', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '707c999b-d6c6-4ce0-aa96-7634afac7039'	System	24 Oct 2020 20:16:57
User entered 'Does not interfere with activity (2)'	System	24 Oct 2020 20:16:57

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:16:43', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '707c999b-d6c6-4ce0-aa96-7634afac7039' User entered 'No (N)'	System	24 Oct 2020 20:16:57
	System	24 Oct 2020 20:16:57

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:16:46', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '707c999b-d6c6-4ce0-aa96-7634afac7039' User entered 'No (N)'	System	24 Oct 2020 20:16:57
	System	24 Oct 2020 20:16:57



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:16:49', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '707c999b-d6c6-4ce0-aa96-7634afac7039'	System	24 Oct 2020 20:16:57
User entered 'None (1)'	System	24 Oct 2020 20:16:57

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:16:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '707c999b-d6c6-4ce0-aa96-7634afac7039' User entered '24 Oct 2020 13:16'	System	24 Oct 2020 20:16:57
	System	24 Oct 2020 20:16:57

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 3'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:35:58', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'ad98954f-1c4a-4429-a858-9104a321854e' User entered 'None (1)'	System	26 Oct 2020 04:36:16
	System	26 Oct 2020 04:36:16

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:36:02', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'ad98954f-1c4a-4429-a858-9104a321854e' User entered 'No (N)'	System	26 Oct 2020 04:36:16
	System	26 Oct 2020 04:36:16

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:36:06', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'ad98954f-1c4a-4429-a858-9104a321854e' User entered 'No (N)'	System	26 Oct 2020 04:36:16
	System	26 Oct 2020 04:36:16



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:36:10', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'ad98954f-1c4a-4429-a858-9104a321854e' User entered 'None (1)'	System	26 Oct 2020 04:36:16
	System	26 Oct 2020 04:36:16

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-25T21:36:13', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'ad98954f-1c4a-4429-a858-9104a321854e' User entered '25 Oct 2020 21:36'	System	26 Oct 2020 04:36:16
	System	26 Oct 2020 04:36:16

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 4'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:02:41', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12d6ad2c-2e77-4b94-a6f0-40e960d15935'	System	27 Oct 2020 09:03:24
User entered 'Does not interfere with activity (2)'	System	27 Oct 2020 09:03:24

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:02:48', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12d6ad2c-2e77-4b94-a6f0-40e960d15935'	System	27 Oct 2020 09:03:24
User entered 'No (N)'	System	27 Oct 2020 09:03:24

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:13', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12d6ad2c-2e77-4b94-a6f0-40e960d15935' User entered 'No (N)'	System	27 Oct 2020 09:03:24
	System	27 Oct 2020 09:03:24



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:17', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12d6ad2c-2e77-4b94-a6f0-40e960d15935'	System	27 Oct 2020 09:03:24
User entered 'None (1)'	System	27 Oct 2020 09:03:24

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:23', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12d6ad2c-2e77-4b94-a6f0-40e960d15935' User entered '27 Oct 2020 02:03'	System	27 Oct 2020 09:03:24
	System	27 Oct 2020 09:03:24

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 5'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:32', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '167774ae-2fb2-48ac-be6c-4ea2754eeb13'	System	27 Oct 2020 19:14:54
User entered 'None (1)'	System	27 Oct 2020 19:14:54

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '167774ae-2fb2-48ac-be6c-4ea2754eeb13' User entered 'No (N)'	System	27 Oct 2020 19:14:54
	System	27 Oct 2020 19:14:54

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:45', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '167774ae-2fb2-48ac-be6c-4ea2754eeb13' User entered 'No (N)'	System	27 Oct 2020 19:14:54
	System	27 Oct 2020 19:14:54



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:48', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '167774ae-2fb2-48ac-be6c-4ea2754eeb13'	System	27 Oct 2020 19:14:54
User entered 'None (1)'	System	27 Oct 2020 19:14:54

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:51', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '167774ae-2fb2-48ac-be6c-4ea2754eeb13' User entered '27 Oct 2020 12:14'	System	27 Oct 2020 19:14:54
	System	27 Oct 2020 19:14:54

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 6'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:30', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '5cd4598f-3393-4b99-a5c6-4f1c092dc2e3'	System	28 Oct 2020 19:55:57
User entered 'None (1)'	System	28 Oct 2020 19:55:57

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:32', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '5cd4598f-3393-4b99-a5c6-4f1c092dc2e3' User entered 'No (N)'	System	28 Oct 2020 19:55:57
	System	28 Oct 2020 19:55:57

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:36', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '5cd4598f-3393-4b99-a5c6-4f1c092dc2e3' User entered 'No (N)'	System	28 Oct 2020 19:55:57
	System	28 Oct 2020 19:55:57



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:40', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '5cd4598f-3393-4b99-a5c6-4f1c092dc2e3'	System	28 Oct 2020 19:55:57
User entered 'None (1)'	System	28 Oct 2020 19:55:57

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:55', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '5cd4598f-3393-4b99-a5c6-4f1c092dc2e3' User entered '28 Oct 2020 12:55'	System	28 Oct 2020 19:55:57
	System	28 Oct 2020 19:55:57

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 7'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:10:55', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c4d7dc7e-1c78-4f97-b4e7-c490581d8f95'	System	29 Oct 2020 19:11:11
User entered 'None (1)'	System	29 Oct 2020 19:11:11

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:10:59', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c4d7dc7e-1c78-4f97-b4e7-c490581d8f95'	System	29 Oct 2020 19:11:11
User entered 'No (N)'	System	29 Oct 2020 19:11:11

US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:02', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c4d7dc7e-1c78-4f97-b4e7-c490581d8f95'	System	29 Oct 2020 19:11:11
User entered 'No (N)'	System	29 Oct 2020 19:11:11



US3682211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:06', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c4d7dc7e-1c78-4f97-b4e7-c490581d8f95'	System	29 Oct 2020 19:11:11
User entered 'None (1)'	System	29 Oct 2020 19:11:11

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:09', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c4d7dc7e-1c78-4f97-b4e7-c490581d8f95' User entered '29 Oct 2020 12:11'	System	29 Oct 2020 19:11:11
	System	29 Oct 2020 19:11:11

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:13:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763' User entered 'None (0)'	System	23 Oct 2020 17:14:12
	System	23 Oct 2020 17:14:12

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:13:44', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763' User entered 'None (0)'	System	23 Oct 2020 17:14:12
	System	23 Oct 2020 17:14:12

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:13:49', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763' User entered 'None (0)'	System	23 Oct 2020 17:14:12
	System	23 Oct 2020 17:14:12



US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:13:52', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763' User entered 'None (0)'	System	23 Oct 2020 17:14:12
	System	23 Oct 2020 17:14:12

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:13:55', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763' User entered 'None (0)'	System	23 Oct 2020 17:14:12
	System	23 Oct 2020 17:14:12

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:13:58', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763' User entered 'None (0)'	System	23 Oct 2020 17:14:12
	System	23 Oct 2020 17:14:12

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:14:04', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763'	System	23 Oct 2020 17:14:12
User entered 'No (N)'	System	23 Oct 2020 17:14:12

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T10:14:10', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2904ad6e-99b1-4619-92ea-7e0832120763' User entered '23 Oct 2020 10:14'	System	23 Oct 2020 17:14:12
	System	23 Oct 2020 17:14:12

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 09:38'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 12:08'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 16:36:44



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:45', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702' User entered 'None (0)'	System	24 Oct 2020 00:30:11
	System	24 Oct 2020 00:30:11

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:47', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702' User entered 'None (0)'	System	24 Oct 2020 00:30:11
	System	24 Oct 2020 00:30:11

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:51', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702' User entered 'None (0)'	System	24 Oct 2020 00:30:11
	System	24 Oct 2020 00:30:11

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:54', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702' User entered 'None (0)'	System	24 Oct 2020 00:30:11
	System	24 Oct 2020 00:30:11

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:29:58', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702' User entered 'None (0)'	System	24 Oct 2020 00:30:11
	System	24 Oct 2020 00:30:11

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:30:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702' User entered 'None (0)'	System	24 Oct 2020 00:30:11
	System	24 Oct 2020 00:30:11

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:30:04', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702'	System	24 Oct 2020 00:30:11
User entered 'No (N)'	System	24 Oct 2020 00:30:11

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-23T17:30:07', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2382d419-5bde-416f-97f6-138ee35b4702'	System	24 Oct 2020 00:30:11
User entered '23 Oct 2020 17:30'	System	24 Oct 2020 00:30:11



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Oct 2020 13:03'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 2'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:16:59', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08' User entered 'None (0)'	System	24 Oct 2020 20:17:26
	System	24 Oct 2020 20:17:26

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:17:03', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08'	System	24 Oct 2020 20:17:26
User entered 'No interference with activity (1)'	System	24 Oct 2020 20:17:26

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:17:09', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08'	System	24 Oct 2020 20:17:26
User entered 'No interference with activity (1)'	System	24 Oct 2020 20:17:26

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:17:12', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08' User entered 'None (0)'	System	24 Oct 2020 20:17:26
	System	24 Oct 2020 20:17:26

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:17:14', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08' User entered 'None (0)'	System	24 Oct 2020 20:17:26
	System	24 Oct 2020 20:17:26



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:17:18', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08'	System	24 Oct 2020 20:17:26
User entered 'No interference with activity (1)'	System	24 Oct 2020 20:17:26

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:17:22', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08'	System	24 Oct 2020 20:17:26
User entered 'No (N)'	System	24 Oct 2020 20:17:26

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-24T13:17:24', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c9dcb32f-da08-40bf-a57e-8c0643bd2d08' User entered '24 Oct 2020 13:17'	System	24 Oct 2020 20:17:26
	System	24 Oct 2020 20:17:26

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 3'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31



US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:36:44



US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 4'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:29', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8' User entered 'None (0)'	System	27 Oct 2020 09:04:07
	System	27 Oct 2020 09:04:07

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:38', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8'	System	27 Oct 2020 09:04:07
User entered 'No interference with activity (1)'	System	27 Oct 2020 09:04:07

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:45', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8' User entered 'None (0)'	System	27 Oct 2020 09:04:07
	System	27 Oct 2020 09:04:07

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:49', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8' User entered 'None (0)'	System	27 Oct 2020 09:04:07
	System	27 Oct 2020 09:04:07

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8' User entered 'None (0)'	System	27 Oct 2020 09:04:07
	System	27 Oct 2020 09:04:07

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:03:56', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8'	System	27 Oct 2020 09:04:07
User entered 'No interference with activity (1)'	System	27 Oct 2020 09:04:07

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:04:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8'	System	27 Oct 2020 09:04:07
User entered 'No (N)'	System	27 Oct 2020 09:04:07



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T02:04:03', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6e61ead6-0f88-44cb-91b7-441fd4a2f3d8' User entered '27 Oct 2020 02:04'	System	27 Oct 2020 09:04:07
	System	27 Oct 2020 09:04:07

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 5'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:14:58', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad' User entered 'None (0)'	System	27 Oct 2020 19:15:31
	System	27 Oct 2020 19:15:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:15:02', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad'	System	27 Oct 2020 19:15:31
User entered 'No interference with activity (1)'	System	27 Oct 2020 19:15:31

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:15:08', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad' User entered 'None (0)'	System	27 Oct 2020 19:15:31
	System	27 Oct 2020 19:15:31

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:15:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad' User entered 'None (0)'	System	27 Oct 2020 19:15:31
	System	27 Oct 2020 19:15:31



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:15:18', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad' User entered 'None (0)'	System	27 Oct 2020 19:15:31
	System	27 Oct 2020 19:15:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:15:21', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad' User entered 'None (0)'	System	27 Oct 2020 19:15:31
	System	27 Oct 2020 19:15:31

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:15:24', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad' User entered 'No (N)'	System	27 Oct 2020 19:15:31
	System	27 Oct 2020 19:15:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-27T12:15:29', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd7780b9a-ae15-4b2f-89d0-ab6f950462ad' User entered '27 Oct 2020 12:15'	System	27 Oct 2020 19:15:31
	System	27 Oct 2020 19:15:31

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 6'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:55:59', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe' User entered 'None (0)'	System	28 Oct 2020 19:56:24
	System	28 Oct 2020 19:56:24



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:56:03', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe'	System	28 Oct 2020 19:56:24
User entered 'No interference with activity (1)'	System	28 Oct 2020 19:56:24

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:56:07', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe' User entered 'None (0)'	System	28 Oct 2020 19:56:24
	System	28 Oct 2020 19:56:24

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:56:09', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe' User entered 'None (0)'	System	28 Oct 2020 19:56:24
	System	28 Oct 2020 19:56:24

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:56:11', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe' User entered 'None (0)'	System	28 Oct 2020 19:56:24
	System	28 Oct 2020 19:56:24

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:56:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe'	System	28 Oct 2020 19:56:24
User entered 'No interference with activity (1)'	System	28 Oct 2020 19:56:24

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:56:17', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe' User entered 'No (N)'	System	28 Oct 2020 19:56:24
	System	28 Oct 2020 19:56:24

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-28T12:56:20', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '482cc1eb-dfd5-42e2-b9c9-5088533da9fe' User entered '28 Oct 2020 12:56'	System	28 Oct 2020 19:56:24
	System	28 Oct 2020 19:56:24

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 16:36:44



**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	23 Oct 2020 16:36:44
User entered 'Day 7'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered 'None (0)'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:17', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered 'None (0)'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:18', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered 'None (0)'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35

US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:20', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered 'None (0)'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:21', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered 'None (0)'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:23', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered 'None (0)'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35



US3682211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:24', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered 'No (N)'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-10-29T12:11:30', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd90b6250-1486-447b-a2f1-d639a405d5bd' User entered '29 Oct 2020 12:11'	System	29 Oct 2020 19:11:35
	System	29 Oct 2020 19:11:35

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 16:36:44

**US3682211**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:13:33

**US3682211**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '30 Oct 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:13:33

**US3682211**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:13:33

**US3682211**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	Susan Reed (b) (4)	06 Nov 2020 23:13:33



US3682211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:12:46

**US3682211**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	06 Nov 2020 23:12:46

**US3682211**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:13:13

**US3682211**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '6 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:13:13

**US3682211**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:13:13

**US3682211**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	Susan Reed (b) (4)	06 Nov 2020 23:13:13

**US3682211**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	06 Nov 2020 23:13:18

**US3682211**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	06 Nov 2020 23:13:18



**US3682211**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	05 Dec 2020 00:15:58

**US3682211**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '14 Nov 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	05 Dec 2020 00:15:58

**US3682211**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	05 Dec 2020 00:15:58

**US3682211**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	Susan Reed (b) (4)	05 Dec 2020 00:15:58

US3682211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:26:40

**US3682211**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	20 Nov 2020 21:26:40

**US3682211**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:41

**US3682211**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:41



**US3682211**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:41

**US3682211**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'VISIT2'	System	20 Nov 2020 21:27:41

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '12:43'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '20 Nov 2020 12:43'	System	20 Nov 2020 22:09:50

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50



US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '70'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'bpm'	System	20 Nov 2020 22:09:50

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:09:50

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'breaths/min'	System	20 Nov 2020 22:09:50

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 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)	23 Nov 2020 12:32:54
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 22:52:41
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 22:52:06
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Nov 2020 22:09:50
User entered '70'	(b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	20 Nov 2020 22:09:50



US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 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)	23 Nov 2020 12:33:04
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 22:52:08
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Nov 2020 22:09:50
User entered '58'	(b) (4), (b) (6)	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	20 Nov 2020 22:09:50

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Nov 2020 22:11:51

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '13:46'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '20 Nov 2020 13:46'	System	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51



US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '68'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'bpm'	System	20 Nov 2020 22:11:51

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '14'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'breaths/min'	System	20 Nov 2020 22:11:51

US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '96'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	20 Nov 2020 22:11:51



US3682211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 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)	23 Nov 2020 12:33:31
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 22:52:20
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		20 Nov 2020 22:11:51
User entered '51'	(b) (4), (b) (6)	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	20 Nov 2020 22:11:51

**US3682211**

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

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:55

US3682211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:55

**US3682211**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:21

**US3682211**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:21

US3682211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:21

US3682211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'MRNA-1273 OR PLACEBO'	System	20 Nov 2020 21:27:21



**US3682211**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:21

US3682211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '13:12'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:21

**US3682211**

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

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '20 Nov 2020 13:12'	System	20 Nov 2020 21:27:21

US3682211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:27:21

US3682211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'ONCE'	System	20 Nov 2020 21:27:21

US3682211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'INTRAMUSCULAR'	System	20 Nov 2020 21:27:21

**US3682211**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:38:54

**US3682211**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:38:54



**US3682211**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '13:02'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:38:54

**US3682211**

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

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '20 Nov 2020 13:02'	System	21 Nov 2020 00:38:54

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 23:05:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:39:25

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Nov 2020 00:39:25

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:39:25

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '13:04'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:39:25

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '20 Nov 2020 13:04'	System	21 Nov 2020 00:39:25

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Nov 2020 00:39:25



**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:39:25

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:05:54**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:39:25

**US3682211**

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

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered empty.	System	21 Nov 2020 00:39:25

US3682211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:28:04

**US3682211**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '1'	System	20 Nov 2020 21:28:04

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T16:02:04', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4599b73e-4d38-4cbe-93f7-733f2e4098b7'	System	21 Nov 2020 00:02:23
User entered 'Yes (Y)'	System	21 Nov 2020 00:02:23

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T16:02:12', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4599b73e-4d38-4cbe-93f7-733f2e4098b7' User entered '98.5'	System	21 Nov 2020 00:02:23
	System	21 Nov 2020 00:02:23



US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T16:02:16', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4599b73e-4d38-4cbe-93f7-733f2e4098b7'	System	21 Nov 2020 00:02:23
User entered 'No (N)'	System	21 Nov 2020 00:02:23

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T16:02:19', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4599b73e-4d38-4cbe-93f7-733f2e4098b7' User entered '20 Nov 2020 16:02'	System	21 Nov 2020 00:02:23
	System	21 Nov 2020 00:02:23

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 13:32'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 16:02'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 1, after vaccination (at home)'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:07:19', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c17f7976-1ba1-40d3-9005-ecdaffb22e93'	System	21 Nov 2020 04:07:44
User entered 'Yes (Y)'	System	21 Nov 2020 04:07:44

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:07:25', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c17f7976-1ba1-40d3-9005-ecdaffb22e93'	System	21 Nov 2020 04:07:44
User entered '98.4'	System	21 Nov 2020 04:07:44

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:07:30', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c17f7976-1ba1-40d3-9005-ecdaffb22e93'	System	21 Nov 2020 04:07:44
User entered 'No (N)'	System	21 Nov 2020 04:07:44



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:07:40', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c17f7976-1ba1-40d3-9005-ecdaffb22e93' User entered '20 Nov 2020 20:07'	System	21 Nov 2020 04:07:44
	System	21 Nov 2020 04:07:44

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 16:57'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '21 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 2'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31



US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:05:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 3'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:20:46', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '82d602e5-29aa-4471-8f52-a3f17c2aaf22'	System	22 Nov 2020 20:21:06
User entered 'Yes (Y)'	System	22 Nov 2020 20:21:06

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:20:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '82d602e5-29aa-4471-8f52-a3f17c2aaf22' User entered '98.2'	System	22 Nov 2020 20:21:06
	System	22 Nov 2020 20:21:06

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:20:56', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '82d602e5-29aa-4471-8f52-a3f17c2aaf22'	System	22 Nov 2020 20:21:06
User entered 'No (N)'	System	22 Nov 2020 20:21:06



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:03', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '82d602e5-29aa-4471-8f52-a3f17c2aaf22'	System	22 Nov 2020 20:21:06
User entered '22 Nov 2020 12:21'	System	22 Nov 2020 20:21:06

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '22 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 4'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:08', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2e1dd849-d283-4644-bc51-4717efcf709a' User entered 'Yes (Y)'	System	24 Nov 2020 06:14:24
	System	24 Nov 2020 06:14:24

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:14', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2e1dd849-d283-4644-bc51-4717efcf709a' User entered '98.3'	System	24 Nov 2020 06:14:24
	System	24 Nov 2020 06:14:24

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:16', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2e1dd849-d283-4644-bc51-4717efcf709a'	System	24 Nov 2020 06:14:24
User entered 'No (N)'	System	24 Nov 2020 06:14:24

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:19', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2e1dd849-d283-4644-bc51-4717efcf709a' User entered '23 Nov 2020 22:14'	System	24 Nov 2020 06:14:24
	System	24 Nov 2020 06:14:24



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:05:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 5'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:14', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '3ab87a7f-1a83-4dcb-9750-ee6c36ef16d3' User entered 'Yes (Y)'	System	24 Nov 2020 20:12:29
	System	24 Nov 2020 20:12:29

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:22', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '3ab87a7f-1a83-4dcb-9750-ee6c36ef16d3' User entered '98.5'	System	24 Nov 2020 20:12:29
	System	24 Nov 2020 20:12:29

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:24', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '3ab87a7f-1a83-4dcb-9750-ee6c36ef16d3'	System	24 Nov 2020 20:12:29
User entered 'No (N)'	System	24 Nov 2020 20:12:29

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:27', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '3ab87a7f-1a83-4dcb-9750-ee6c36ef16d3' User entered '24 Nov 2020 12:12'	System	24 Nov 2020 20:12:29
	System	24 Nov 2020 20:12:29

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Nov 2020 12:00'	System	20 Nov 2020 21:27:21



US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:05:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 6'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:09', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '215786fe-ff84-4ca0-bf54-ca4f17c82b07' User entered 'Yes (Y)'	System	26 Nov 2020 09:48:24
	System	26 Nov 2020 09:48:24

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '215786fe-ff84-4ca0-bf54-ca4f17c82b07' User entered '98.1'	System	26 Nov 2020 09:48:24
	System	26 Nov 2020 09:48:24

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:18', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '215786fe-ff84-4ca0-bf54-ca4f17c82b07'	System	26 Nov 2020 09:48:24
User entered 'No (N)'	System	26 Nov 2020 09:48:24

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:21', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '215786fe-ff84-4ca0-bf54-ca4f17c82b07' User entered '26 Nov 2020 01:48'	System	26 Nov 2020 09:48:24
	System	26 Nov 2020 09:48:24

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:05:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Nov 2020 11:59'	System	20 Nov 2020 21:27:21



US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 7'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:11', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'f4b2ac96-9b4a-490f-878f-f7eebb5b51e3' User entered 'Yes (Y)'	System	27 Nov 2020 12:11:25
	System	27 Nov 2020 12:11:25

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:16', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'f4b2ac96-9b4a-490f-878f-f7eebb5b51e3' User entered '98.5'	System	27 Nov 2020 12:11:25
	System	27 Nov 2020 12:11:25

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:19', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'f4b2ac96-9b4a-490f-878f-f7eebb5b51e3'	System	27 Nov 2020 12:11:25
User entered 'No (N)'	System	27 Nov 2020 12:11:25

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:21', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'f4b2ac96-9b4a-490f-878f-f7eebb5b51e3' User entered '27 Nov 2020 04:11'	System	27 Nov 2020 12:11:25
	System	27 Nov 2020 12:11:25

US3682211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:05:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Nov 2020 21:27:21



US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 13:32'	System	20 Nov 2020 21:27:21



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 16:02'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 1, after vaccination (at home)'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:07:48', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6a82d569-51e4-41a6-a8f7-553325853120'	System	21 Nov 2020 04:08:13
User entered 'Does not interfere with activity (2)'	System	21 Nov 2020 04:08:13

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:07:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6a82d569-51e4-41a6-a8f7-553325853120' User entered 'No (N)'	System	21 Nov 2020 04:08:13
	System	21 Nov 2020 04:08:13

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:01', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6a82d569-51e4-41a6-a8f7-553325853120' User entered 'No (N)'	System	21 Nov 2020 04:08:13
	System	21 Nov 2020 04:08:13

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:05', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6a82d569-51e4-41a6-a8f7-553325853120' User entered 'None (1)'	System	21 Nov 2020 04:08:13
	System	21 Nov 2020 04:08:13

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:10', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6a82d569-51e4-41a6-a8f7-553325853120' User entered '20 Nov 2020 20:08'	System	21 Nov 2020 04:08:13
	System	21 Nov 2020 04:08:13

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 16:57'	System	20 Nov 2020 21:27:21



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '21 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 2'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 3'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:09', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a39fcf93-2055-4e69-8213-38fc2938a63d'	System	22 Nov 2020 20:21:24
User entered 'None (1)'	System	22 Nov 2020 20:21:24

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:12', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a39fcf93-2055-4e69-8213-38fc2938a63d' User entered 'No (N)'	System	22 Nov 2020 20:21:24
	System	22 Nov 2020 20:21:24

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:14', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a39fcf93-2055-4e69-8213-38fc2938a63d' User entered 'No (N)'	System	22 Nov 2020 20:21:24
	System	22 Nov 2020 20:21:24

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:17', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a39fcf93-2055-4e69-8213-38fc2938a63d'	System	22 Nov 2020 20:21:24
User entered 'None (1)'	System	22 Nov 2020 20:21:24



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:21', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a39fcf93-2055-4e69-8213-38fc2938a63d' User entered '22 Nov 2020 12:21'	System	22 Nov 2020 20:21:24
	System	22 Nov 2020 20:21:24

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '22 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 4'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:22', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'cdfbf4f2-5608-4968-93e6-89f9b4373c89'	System	24 Nov 2020 06:14:35
User entered 'None (1)'	System	24 Nov 2020 06:14:35

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:25', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'cdfbf4f2-5608-4968-93e6-89f9b4373c89'	System	24 Nov 2020 06:14:35
User entered 'No (N)'	System	24 Nov 2020 06:14:35

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:27', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'cdfbf4f2-5608-4968-93e6-89f9b4373c89'	System	24 Nov 2020 06:14:35
User entered 'No (N)'	System	24 Nov 2020 06:14:35

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:29', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'cdfbf4f2-5608-4968-93e6-89f9b4373c89'	System	24 Nov 2020 06:14:35
User entered 'None (1)'	System	24 Nov 2020 06:14:35



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:33', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'cdfbf4f2-5608-4968-93e6-89f9b4373c89' User entered '23 Nov 2020 22:14'	System	24 Nov 2020 06:14:35
	System	24 Nov 2020 06:14:35

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 5'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:30', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '9aead4da-3db9-4c49-a041-edab86cbc853'	System	24 Nov 2020 20:12:41
User entered 'None (1)'	System	24 Nov 2020 20:12:41

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:32', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '9aead4da-3db9-4c49-a041-edab86cbc853'	System	24 Nov 2020 20:12:41
User entered 'No (N)'	System	24 Nov 2020 20:12:41

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:35', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '9aead4da-3db9-4c49-a041-edab86cbc853'	System	24 Nov 2020 20:12:41
User entered 'No (N)'	System	24 Nov 2020 20:12:41

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:36', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '9aead4da-3db9-4c49-a041-edab86cbc853'	System	24 Nov 2020 20:12:41
User entered 'None (1)'	System	24 Nov 2020 20:12:41



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '9aead4da-3db9-4c49-a041-edab86cbc853'	System	24 Nov 2020 20:12:41
User entered '24 Nov 2020 12:12'	System	24 Nov 2020 20:12:41

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 6'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:25', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '30ae7160-cd1e-4db5-a890-9cc24966d05e'	System	26 Nov 2020 09:48:39
User entered 'None (1)'	System	26 Nov 2020 09:48:39

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:27', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '30ae7160-cd1e-4db5-a890-9cc24966d05e' User entered 'No (N)'	System	26 Nov 2020 09:48:39
	System	26 Nov 2020 09:48:39

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:31', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '30ae7160-cd1e-4db5-a890-9cc24966d05e' User entered 'No (N)'	System	26 Nov 2020 09:48:39
	System	26 Nov 2020 09:48:39

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:33', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '30ae7160-cd1e-4db5-a890-9cc24966d05e'	System	26 Nov 2020 09:48:39
User entered 'None (1)'	System	26 Nov 2020 09:48:39



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:36', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '30ae7160-cd1e-4db5-a890-9cc24966d05e' User entered '26 Nov 2020 01:48'	System	26 Nov 2020 09:48:39
	System	26 Nov 2020 09:48:39

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 7'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:26', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'efe0ae60-1c73-41bc-a8c6-bc0cc0f7de32'	System	27 Nov 2020 12:11:36
User entered 'None (1)'	System	27 Nov 2020 12:11:36

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:27', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'efe0ae60-1c73-41bc-a8c6-bc0cc0f7de32'	System	27 Nov 2020 12:11:36
User entered 'No (N)'	System	27 Nov 2020 12:11:36

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:29', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'efe0ae60-1c73-41bc-a8c6-bc0cc0f7de32'	System	27 Nov 2020 12:11:36
User entered 'No (N)'	System	27 Nov 2020 12:11:36

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:31', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'efe0ae60-1c73-41bc-a8c6-bc0cc0f7de32'	System	27 Nov 2020 12:11:36
User entered 'None (1)'	System	27 Nov 2020 12:11:36



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'efe0ae60-1c73-41bc-a8c6-bc0cc0f7de32' User entered '27 Nov 2020 04:11'	System	27 Nov 2020 12:11:36
	System	27 Nov 2020 12:11:36

US3682211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:05:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31



US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 13:32'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 16:02'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 1, after vaccination (at home)'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:18', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06'	System	21 Nov 2020 04:08:53
User entered 'No interference with activity (1)'	System	21 Nov 2020 04:08:53



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:25', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06'	System	21 Nov 2020 04:08:53
User entered 'No interference with activity (1)'	System	21 Nov 2020 04:08:53

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:31', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06'	System	21 Nov 2020 04:08:53
User entered 'No interference with activity (1)'	System	21 Nov 2020 04:08:53

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:37', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06' User entered 'None (0)'	System	21 Nov 2020 04:08:53
	System	21 Nov 2020 04:08:53

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:40', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06' User entered 'None (0)'	System	21 Nov 2020 04:08:53
	System	21 Nov 2020 04:08:53

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:43', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06'	System	21 Nov 2020 04:08:53
User entered 'No interference with activity (1)'	System	21 Nov 2020 04:08:53

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:46', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06'	System	21 Nov 2020 04:08:53
User entered 'No (N)'	System	21 Nov 2020 04:08:53

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-20T20:08:51', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '358abf6e-8b5b-4457-8cbd-17da747d9d06' User entered '20 Nov 2020 20:08'	System	21 Nov 2020 04:08:53
	System	21 Nov 2020 04:08:53

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '20 Nov 2020 16:57'	System	20 Nov 2020 21:27:21



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '21 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 2'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31



US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:05:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '21 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '22 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 3'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:27', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1' User entered 'None (0)'	System	22 Nov 2020 20:21:47
	System	22 Nov 2020 20:21:47

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:29', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1' User entered 'None (0)'	System	22 Nov 2020 20:21:47
	System	22 Nov 2020 20:21:47

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:31', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1' User entered 'None (0)'	System	22 Nov 2020 20:21:47
	System	22 Nov 2020 20:21:47



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:33', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1' User entered 'None (0)'	System	22 Nov 2020 20:21:47
	System	22 Nov 2020 20:21:47

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:35', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1' User entered 'None (0)'	System	22 Nov 2020 20:21:47
	System	22 Nov 2020 20:21:47

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:36', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1' User entered 'None (0)'	System	22 Nov 2020 20:21:47
	System	22 Nov 2020 20:21:47

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:41', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1'	System	22 Nov 2020 20:21:47
User entered 'No (N)'	System	22 Nov 2020 20:21:47

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-22T12:21:45', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '2456fa09-6c3f-4e58-9fe2-2ba88f7121d1' User entered '22 Nov 2020 12:21'	System	22 Nov 2020 20:21:47
	System	22 Nov 2020 20:21:47

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '22 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 4'	System	20 Nov 2020 21:27:21



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:36', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered 'None (0)'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:38', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered 'None (0)'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:42', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered 'None (0)'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:44', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered 'None (0)'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:46', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered 'None (0)'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:48', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered 'None (0)'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:49', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered 'No (N)'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-23T22:14:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77ae7d39-ddb4-4650-8552-12ba846f1ff7' User entered '23 Nov 2020 22:14'	System	24 Nov 2020 06:14:56
	System	24 Nov 2020 06:14:56



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '23 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 5'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:43', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered 'None (0)'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:45', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered 'None (0)'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:47', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered 'None (0)'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:49', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered 'None (0)'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:50', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered 'None (0)'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:52', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered 'None (0)'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered 'No (N)'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-24T12:12:56', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'd73bedf6-9c75-471d-83c1-4263c898198d' User entered '24 Nov 2020 12:12'	System	24 Nov 2020 20:12:59
	System	24 Nov 2020 20:12:59

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '24 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 6'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:40', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc' User entered 'None (0)'	System	26 Nov 2020 09:49:00
	System	26 Nov 2020 09:49:00

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:42', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc' User entered 'None (0)'	System	26 Nov 2020 09:49:00
	System	26 Nov 2020 09:49:00



US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:44', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc' User entered 'None (0)'	System	26 Nov 2020 09:49:00
	System	26 Nov 2020 09:49:00

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:46', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc' User entered 'None (0)'	System	26 Nov 2020 09:49:00
	System	26 Nov 2020 09:49:00

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:48', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc' User entered 'None (0)'	System	26 Nov 2020 09:49:00
	System	26 Nov 2020 09:49:00

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:50', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc' User entered 'None (0)'	System	26 Nov 2020 09:49:00
	System	26 Nov 2020 09:49:00

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:52', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc'	System	26 Nov 2020 09:49:00
User entered 'No (N)'	System	26 Nov 2020 09:49:00

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-26T01:48:56', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'c6a44df9-3b8f-45b5-b56f-1c85d9ec24fc' User entered '26 Nov 2020 01:48'	System	26 Nov 2020 09:49:00
	System	26 Nov 2020 09:49:00

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '25 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Nov 2020 11:59'	System	20 Nov 2020 21:27:21



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
Data entry locked.	System	20 Nov 2020 21:27:21
User entered 'Day 7'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:37', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737' User entered 'None (0)'	System	27 Nov 2020 12:11:52
	System	27 Nov 2020 12:11:52

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737' User entered 'None (0)'	System	27 Nov 2020 12:11:52
	System	27 Nov 2020 12:11:52

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:40', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737' User entered 'None (0)'	System	27 Nov 2020 12:11:52
	System	27 Nov 2020 12:11:52

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:42', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737' User entered 'None (0)'	System	27 Nov 2020 12:11:52
	System	27 Nov 2020 12:11:52

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:44', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737' User entered 'None (0)'	System	27 Nov 2020 12:11:52
	System	27 Nov 2020 12:11:52

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:45', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737' User entered 'None (0)'	System	27 Nov 2020 12:11:52
	System	27 Nov 2020 12:11:52

US3682211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:05:54

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 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:47', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737'	System	27 Nov 2020 12:11:52
User entered 'No (N)'	System	27 Nov 2020 12:11:52



**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (EDF05B5B-5D2B-4A40-8432-518BA09ED22D)', Time: '2020-11-27T04:11:50', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '77d86ea7-8a6d-4ddf-b893-9c701a3b2737' User entered '27 Nov 2020 04:11'	System	27 Nov 2020 12:11:52
	System	27 Nov 2020 12:11:52

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '26 Nov 2020 12:00'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 23:05:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:05:31
User entered '27 Nov 2020 11:59'	System	20 Nov 2020 21:27:21

**US3682211**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Nov 2020 02:06:15

**US3682211**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Nov 2020 02:06:15

**US3682211**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Nov 2020 02:06:15

**US3682211**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Nov 2020 02:06:15

**US3682211**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	19 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Nov 2020 02:06:20



**US3682211**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	28 Nov 2020 02:06:20

**US3682211**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	04 Dec 2020 21:27:13

**US3682211**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered '4 Dec 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	04 Dec 2020 21:27:13

**US3682211**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4) (b) (4)	04 Dec 2020 21:27:13

**US3682211**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered empty.	Susan Reed (b) (4)	04 Dec 2020 21:27:13

**US3682211**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	04 Dec 2020 21:27:17

**US3682211**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	04 Dec 2020 21:27:17

**US3682211**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Dec 2020 21:38:49



**US3682211**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered '11 Dec 2020'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Dec 2020 21:38:49

**US3682211**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Susan Reed (b) (4)	11 Dec 2020 21:38:49

**US3682211**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered empty.	Susan Reed (b) (4)	11 Dec 2020 21:38:49

**US3682211**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:28
User entered 'Yes (Y)'	(b) (4) Susan Reed (b) (4) (b) (4)	11 Dec 2020 21:38:53

**US3682211**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	11 Dec 2020 21:38:53

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:10:24

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Dec 2020'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:10:24

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Clinic (Clinic)'	(b) (4) Schuyler Thomas (b) (4) (b) (4)	23 Dec 2020 23:10:24



**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'VISIT3'	System	23 Dec 2020 23:10:24

US3682211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

US3682211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Dec 2020'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '15:01'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '23 Dec 2020 15:01'	System	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '98.4' F	Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

US3682211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Oral (Oral)'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered empty.	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33



**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '79'	Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'bpm'	System	23 Dec 2020 23:18:33

US3682211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '18'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'breaths/min'	System	23 Dec 2020 23:18:33

US3682211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '98'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	23 Dec 2020 23:18:33

US3682211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '65'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:18:33

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'mmHg'	System	23 Dec 2020 23:18:33



**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18

US3682211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:11:04

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '23 Dec 2020'	Schuyler Thomas (b) (4)	23 Dec 2020 23:11:04

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Dec 2020 00:24:07

US3682211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User closed query 'Per GCL Lab Reconciliation: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 06:56:23
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
Query 'Per GCL Lab Reconciliation: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' answered with 'Sample shipped 1/5/21 accession number: 1F60NJW. Per preclarus shipment received 1/6/21; Per fedex AWB: 1002286101960004107000939474283628 signed and received by (b) (6) on 1/6/21' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 16:51:05
User opened query 'Per GCL Lab Reconciliation: Response to previous query: Response noted, however please provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:35:14
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 23Dec2020. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:16:10
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 23Dec2020. Please clarify and update if appropriate.' answered with 'Due to holiday shipping restrictions, closures and staffing, samples shipped on 1/5/2021 see accession# 1F60NJW' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 01:01:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Per GCL, no immunogenicity sample was received for the Visit 3 Day 57 on 23Dec2020. Please clarify and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 14:24:08

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Dec 2020'	(b) (4), (b) (6)	24 Dec 2020 00:24:07

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered '15:11'	(b) (4) (b) (4), (b) (6)	24 Dec 2020 00:24:07



**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered '23 Dec 2020 15:11'	System	24 Dec 2020 00:24:07

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	12 Feb 2021 19:36:32
User entered 'Yes (Y)'	(b) (4) Schuyler Thomas (b) (4)	23 Dec 2020 23:10:29

**US3682211**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	23 Dec 2020 23:10:29

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2020-12-23T15:34:30', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '02b1ee82-00a1-4b26-b114-86018bdc64d3'	System	23 Dec 2020 23:34:46
User entered 'No (N)'	System	23 Dec 2020 23:34:46

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2020-12-23T15:34:33', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '02b1ee82-00a1-4b26-b114-86018bdc64d3'	System	23 Dec 2020 23:34:46
User entered 'No (N)'	System	23 Dec 2020 23:34:46

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2020-12-23T15:34:41', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '02b1ee82-00a1-4b26-b114-86018bdc64d3'	System	23 Dec 2020 23:34:46
User entered '23 Dec 2020 15:34:41'	System	23 Dec 2020 23:34:46

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2020-12-27T15:23:42', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '8c0ee8c4-4ffd-422d-a73c-fb53c7682258'	System	27 Dec 2020 23:23:55
User entered 'No (N)'	System	27 Dec 2020 23:23:55

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2020-12-27T15:23:46', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '8c0ee8c4-4ffd-422d-a73c-fb53c7682258'	System	27 Dec 2020 23:23:55
User entered 'No (N)'	System	27 Dec 2020 23:23:55

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2020-12-27T15:23:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '8c0ee8c4-4ffd-422d-a73c-fb53c7682258'	System	27 Dec 2020 23:23:55
User entered '27 Dec 2020 15:23:53'	System	27 Dec 2020 23:23:55

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-04T02:52:08', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'bd524d1b-443c-4145-adbf-d47e29592af8'	System	04 Jan 2021 10:52:45
User entered 'Yes (Y)'	System	04 Jan 2021 10:52:45

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-01-04T02:52:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'bd524d1b-443c-4145-adbf-d47e29592af8'	System	04 Jan 2021 10:52:45
User entered 'No (N)'	System	04 Jan 2021 10:52:45

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-04T02:52:24', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'bd524d1b-443c-4145-adbf-d47e29592af8'	System	04 Jan 2021 10:52:45
User entered 'No (N)'	System	04 Jan 2021 10:52:45

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-04T02:52:31', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'bd524d1b-443c-4145-adbf-d47e29592af8'	System	04 Jan 2021 10:52:45
User entered 'No (N)'	System	04 Jan 2021 10:52:45

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-04T02:52:42', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'bd524d1b-443c-4145-adbf-d47e29592af8' User entered '04 Jan 2021 02:52:42'	System	04 Jan 2021 10:52:45
	System	04 Jan 2021 10:52:45

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-10T04:17:05', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7a8d3689-7955-4623-83a2-efee1f21fe8'	System	10 Jan 2021 12:17:41
User entered 'Yes (Y)'	System	10 Jan 2021 12:17:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-01-10T04:17:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7a8d3689-7955-4623-83a2-efee1f21fe8'	System	10 Jan 2021 12:17:41
User entered 'No (N)'	System	10 Jan 2021 12:17:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-10T04:17:21', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7a8d3689-7955-4623-83a2-efee1f21fe8'	System	10 Jan 2021 12:17:41
User entered 'No (N)'	System	10 Jan 2021 12:17:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-10T04:17:32', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7a8d3689-7955-4623-83a2-efee1f21fe8'	System	10 Jan 2021 12:17:41
User entered 'No (N)'	System	10 Jan 2021 12:17:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-10T04:17:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7a8d3689-7955-4623-83a2-efee1f21fe8'	System	10 Jan 2021 12:17:41
User entered '10 Jan 2021 04:17:39'	System	10 Jan 2021 12:17:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-17T12:35:10', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4b32f0c5-76c5-4ef9-86a7-1d9ac708dc2d'	System	17 Jan 2021 20:35:56
User entered 'Yes (Y)'	System	17 Jan 2021 20:35:56

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-01-17T12:35:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4b32f0c5-76c5-4ef9-86a7-1d9ac708dc2d'	System	17 Jan 2021 20:35:56
User entered 'No (N)'	System	17 Jan 2021 20:35:56

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-17T12:35:22', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4b32f0c5-76c5-4ef9-86a7-1d9ac708dc2d'	System	17 Jan 2021 20:35:56
User entered 'No (N)'	System	17 Jan 2021 20:35:56

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-17T12:35:35', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4b32f0c5-76c5-4ef9-86a7-1d9ac708dc2d'	System	17 Jan 2021 20:35:56
User entered 'Yes (Y)'	System	17 Jan 2021 20:35:56

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-17T12:35:42', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4b32f0c5-76c5-4ef9-86a7-1d9ac708dc2d'	System	17 Jan 2021 20:35:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 20:35:56

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-17T12:35:46', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '4b32f0c5-76c5-4ef9-86a7-1d9ac708dc2d' User entered '17 Jan 2021 12:35:46'	System	17 Jan 2021 20:35:56

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-26T22:43:44', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered 'Yes (Y)'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-01-26T22:43:54', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered 'No (N)'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-26T22:44:15', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered 'Yes (Y)'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '1'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '1'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '1'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '1'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '1'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '1'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:34', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '0'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:40', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-01-26T22:44:45', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered 'Yes (Y)'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:50', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Jan 2021 06:45:06



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-01-26T22:44:54', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '537be4ce-4fe2-48dc-a0f1-8f4641e8bcd2'	System	27 Jan 2021 06:45:06
User entered '26 Jan 2021 22:44:54'	System	27 Jan 2021 06:45:06

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-02-04T13:14:17', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6c475028-7dce-464b-963f-a767b1ecdc4f'	System	04 Feb 2021 21:14:29
User entered 'No (N)'	System	04 Feb 2021 21:14:29

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-02-04T13:14:13', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6c475028-7dce-464b-963f-a767b1ecdc4f'	System	04 Feb 2021 21:14:29
User entered 'No (N)'	System	04 Feb 2021 21:14:29

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-02-04T13:14:26', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '6c475028-7dce-464b-963f-a767b1ecdc4f'	System	04 Feb 2021 21:14:29
User entered '04 Feb 2021 13:14:26'	System	04 Feb 2021 21:14:29

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-02-10T15:29:02', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '8b68d190-e9f3-458d-ab34-d5ceb415a747'	System	10 Feb 2021 23:29:43
User entered 'No (N)'	System	10 Feb 2021 23:29:43

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-02-10T15:29:12', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '8b68d190-e9f3-458d-ab34-d5ceb415a747'	System	10 Feb 2021 23:29:43
User entered 'No (N)'	System	10 Feb 2021 23:29:43

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-02-10T15:29:39', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '8b68d190-e9f3-458d-ab34-d5ceb415a747'	System	10 Feb 2021 23:29:43
User entered '10 Feb 2021 15:29:39'	System	10 Feb 2021 23:29:43

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-02-16T02:24:10', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'acba6f8-76e2-470d-9f0a-42d440609699'	System	16 Feb 2021 10:24:23
User entered 'No (N)'	System	16 Feb 2021 10:24:23

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-02-16T02:24:14', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'acba6f8-76e2-470d-9f0a-42d440609699'	System	16 Feb 2021 10:24:23
User entered 'No (N)'	System	16 Feb 2021 10:24:23

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-02-16T02:24:20', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'acba6f8-76e2-470d-9f0a-42d440609699' User entered '16 Feb 2021 02:24:20'	System	16 Feb 2021 10:24:23
	System	16 Feb 2021 10:24:23

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-02-21T17:00:52', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '98623e14-6980-41a3-a698-6478b9b17ce2'	System	22 Feb 2021 01:01:20
User entered 'No (N)'	System	22 Feb 2021 01:01:20

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-02-21T17:00:55', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '98623e14-6980-41a3-a698-6478b9b17ce2'	System	22 Feb 2021 01:01:20
User entered 'No (N)'	System	22 Feb 2021 01:01:20



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-02-21T17:01:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '98623e14-6980-41a3-a698-6478b9b17ce2'	System	22 Feb 2021 01:01:20
User entered '21 Feb 2021 17:01:00'	System	22 Feb 2021 01:01:20

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-03-02T14:10:53', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1fc6453f-3da2-430b-af7c-b75d1f92a541'	System	02 Mar 2021 22:11:09
User entered 'No (N)'	System	02 Mar 2021 22:11:09

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-03-02T14:10:57', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1fc6453f-3da2-430b-af7c-b75d1f92a541'	System	02 Mar 2021 22:11:09
User entered 'No (N)'	System	02 Mar 2021 22:11:09

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-03-02T14:11:01', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1fc6453f-3da2-430b-af7c-b75d1f92a541'	System	02 Mar 2021 22:11:09
User entered '02 Mar 2021 14:11:01'	System	02 Mar 2021 22:11:09

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-03-08T14:53:25-08:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '0890f6f8-7d59-4f87-9762-3c91f2a929b0'	System	08 Mar 2021 22:53:42
User entered 'No (N)'	System	08 Mar 2021 22:53:42

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-03-08T14:53:29-08:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '0890f6f8-7d59-4f87-9762-3c91f2a929b0'	System	08 Mar 2021 22:53:42
User entered 'No (N)'	System	08 Mar 2021 22:53:42

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-03-08T14:53:37-08:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '0890f6f8-7d59-4f87-9762-3c91f2a929b0' User entered '08 Mar 2021 14:53:37'	System	08 Mar 2021 22:53:42
	System	08 Mar 2021 22:53:42

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-03-18T18:11:54-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7f577ae0-4f17-44a4-a77c-fb9f6f355f86'	System	19 Mar 2021 01:15:41
User entered 'No (N)'	System	19 Mar 2021 01:15:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-03-18T18:11:58-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7f577ae0-4f17-44a4-a77c-fb9f6f355f86'	System	19 Mar 2021 01:15:41
User entered 'No (N)'	System	19 Mar 2021 01:15:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-03-18T18:12:07-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7f577ae0-4f17-44a4-a77c-fb9f6f355f86'	System	19 Mar 2021 01:15:41
User entered '18 Mar 2021 18:12:07'	System	19 Mar 2021 01:15:41

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-03-21T20:38:18-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '85a2e3a0-f68b-4964-8b6d-0452ee010382'	System	22 Mar 2021 03:38:33
User entered 'No (N)'	System	22 Mar 2021 03:38:33

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-03-21T20:38:20-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '85a2e3a0-f68b-4964-8b6d-0452ee010382'	System	22 Mar 2021 03:38:33
User entered 'No (N)'	System	22 Mar 2021 03:38:33



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-03-21T20:38:27-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '85a2e3a0-f68b-4964-8b6d-0452ee010382'	System	22 Mar 2021 03:38:33
User entered '21 Mar 2021 20:38:27'	System	22 Mar 2021 03:38:33

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-03-31T23:23:09-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '489fd0d0-42b1-4d6c-8a86-587b99f2e9db' User entered 'No (N)'	System	03 Apr 2021 16:14:17

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-03-31T23:23:12-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '489fd0d0-42b1-4d6c-8a86-587b99f2e9db'	System	03 Apr 2021 16:14:17
User entered 'No (N)'	System	03 Apr 2021 16:14:17

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-03-31T23:23:15-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '489fd0d0-42b1-4d6c-8a86-587b99f2e9db'	System	03 Apr 2021 16:14:17
User entered '31 Mar 2021 23:23:15'	System	03 Apr 2021 16:14:17

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-04-05T19:42:53-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a42d8f11-db61-4873-ace7-c8f9427ba1a7'	System	06 Apr 2021 02:44:43
User entered 'No (N)'	System	06 Apr 2021 02:44:43

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-04-05T19:43:04-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a42d8f11-db61-4873-ace7-c8f9427ba1a7'	System	06 Apr 2021 02:44:43
User entered 'No (N)'	System	06 Apr 2021 02:44:43

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-04-05T19:43:12-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: 'a42d8f11-db61-4873-ace7-c8f9427ba1a7'	System	06 Apr 2021 02:44:43
User entered '05 Apr 2021 19:43:12'	System	06 Apr 2021 02:44:43

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-04-12T15:32:43-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12b20c4d-f8da-41f2-b0d6-b7202492db06'	System	12 Apr 2021 22:34:24
User entered 'No (N)'	System	12 Apr 2021 22:34:24

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-04-12T15:32:46-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12b20c4d-f8da-41f2-b0d6-b7202492db06'	System	12 Apr 2021 22:34:24
User entered 'No (N)'	System	12 Apr 2021 22:34:24

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-04-12T15:34:11-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '12b20c4d-f8da-41f2-b0d6-b7202492db06'	System	12 Apr 2021 22:34:24
User entered '12 Apr 2021 15:34:11'	System	12 Apr 2021 22:34:24

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-04-18T01:21:36-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1f2709c2-f885-42dd-b85c-7966f712288e'	System	18 Apr 2021 08:21:45
User entered 'No (N)'	System	18 Apr 2021 08:21:45

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-04-18T01:21:39-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1f2709c2-f885-42dd-b85c-7966f712288e'	System	18 Apr 2021 08:21:45
User entered 'No (N)'	System	18 Apr 2021 08:21:45



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-04-18T01:21:43-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1f2709c2-f885-42dd-b85c-7966f712288e'	System	18 Apr 2021 08:21:45
User entered '18 Apr 2021 01:21:43'	System	18 Apr 2021 08:21:45

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-04-25T12:00:51-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '20b5bf5d-d2d0-4802-92ef-10fe38059af2'	System	25 Apr 2021 19:03:20
User entered 'No (N)'	System	25 Apr 2021 19:03:20

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-04-25T12:00:53-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '20b5bf5d-d2d0-4802-92ef-10fe38059af2'	System	25 Apr 2021 19:03:20
User entered 'No (N)'	System	25 Apr 2021 19:03:20

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-04-25T12:02:27-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '20b5bf5d-d2d0-4802-92ef-10fe38059af2'	System	25 Apr 2021 19:03:20
User entered '25 Apr 2021 12:02:27'	System	25 Apr 2021 19:03:20

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[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 (95a09f608e6584f2)', Time: '2021-05-02T09:51:54-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1aae54fc-429e-4c67-b8a5-17a00c2b6813'	System	02 May 2021 16:54:38
User entered 'No (N)'	System	02 May 2021 16:54:38

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Have you been exposed to someone with 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 (95a09f608e6584f2)', Time: '2021-05-02T09:51:55-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1aae54fc-429e-4c67-b8a5-17a00c2b6813'	System	02 May 2021 16:54:38
User entered 'No (N)'	System	02 May 2021 16:54:38

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-05-02T09:54:32-07:00', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '1aae54fc-429e-4c67-b8a5-17a00c2b6813'	System	02 May 2021 16:54:38
User entered '02 May 2021 09:54:32'	System	02 May 2021 16:54:38

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:41:15

**US3682211**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 13:41:15



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:41:15

**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '25 Dec 2022 00:01'	System	20 Nov 2020 13:41:15



**US3682211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:05:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:15
Amendment Manager: User entered '29 Dec 2022 23:59'	System	20 Nov 2020 13:41:15

US3682211

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:05:54**

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)	25 Apr 2021 18:57:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-03-02T14:11:12', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7d0f92e7-3c46-4ce7-b0d3-36a1831de782'	System	02 Mar 2021 22:11:20
User entered 'No (N)'	System	02 Mar 2021 22:11:20

**US3682211**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:57:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95a09f608e6584f2)', Time: '2021-03-02T14:11:16', User OID: 'PatientReportedOutcome (US3682211)', ODM File OID: '7d0f92e7-3c46-4ce7-b0d3-36a1831de782'	System	02 Mar 2021 22:11:20
User entered '02 Mar 2021 14:11:16'	System	02 Mar 2021 22:11:20

**US3682211**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	15 Jan 2021 23:04:28

**US3682211**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered '15 Jan 2021'	Mitchell Stern (b) (4)	15 Jan 2021 23:04:28

**US3682211**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	15 Jan 2021 23:04:28

**US3682211**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered empty.	Mitchell Stern (b) (4)	15 Jan 2021 23:04:28

**US3682211**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	15 Jan 2021 23:04:33



**US3682211**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:36:18
User entered 'I'	System	15 Jan 2021 23:04:33

**US3682211**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	11 Mar 2021 23:20:56

**US3682211**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '17 Feb 2021'	(b) (4) Mitchell Stern (b) (4)	11 Mar 2021 23:20:56

**US3682211**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Contact Made (CONTACT MADE)'	Mitchell Stern (b) (4)	11 Mar 2021 23:20:56

**US3682211**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	11 Mar 2021 23:20:56

**US3682211**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	11 Mar 2021 23:21:32

**US3682211**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User entered '1'	System	11 Mar 2021 23:21:32

**US3682211**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	19 Mar 2021 17:57:11



**US3682211**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '19 Mar 2021'	Mitchell Stern (b) (4)	19 Mar 2021 17:57:11

**US3682211**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4)	19 Mar 2021 17:57:11

**US3682211**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	19 Mar 2021 17:57:11

**US3682211**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	19 Mar 2021 17:57:16

**US3682211**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:34:03
User entered 'I'	System	19 Mar 2021 17:57:16

**US3682211**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:42:53
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	19 Apr 2021 17:41:16
	(b) (4)	

**US3682211**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:42:53
	(b) (4)	
User entered '19 Apr 2021'	Mitchell Stern (b) (4)	19 Apr 2021 17:41:16
	(b) (4)	

**US3682211**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:42:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4) (b) (4)	19 Apr 2021 17:41:16



**US3682211**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:42:53
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	19 Apr 2021 17:41:16
	(b) (4)	

**US3682211**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	20 Apr 2021 18:42:53
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	19 Apr 2021 17:41:22
	(b) (4)	

**US3682211**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 17:41:22

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:05:54

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:09:55
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '25 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:00
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:05:54

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:09:55
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '12:40'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:00
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:05:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:09:55
User entered '25 Jan 2021 12:40'	System	26 Jan 2021 17:07:00

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:05:54

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:09:55
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Safety Call (Safety Call)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:00
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:05:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:09:55
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:00
	(b) (4)	



US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 1 (Day 1)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '17 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:07:59

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:07:59
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 2 (Day 2)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '18 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:16:56

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:16:56
	(b) (4)	

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Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 3 (Day 3)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '19 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

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Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

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Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	



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Form: Symptom Log (3)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:18:39

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

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Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:18:39
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 4 (Day 4)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '20 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:19:24

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:19:24
	(b) (4)	



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Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 5 (Day 5)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '21 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:20:23

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	



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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	



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Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Form: Symptom Log (5)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:20:23
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 6 (Day 6)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '22 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:21:01

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:01
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 7 (Day 7)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '23 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Form: Symptom Log (7)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	



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Form: Symptom Log (7)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:21:38

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	



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Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:21:38
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 8 (Day 8)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '24 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:22:22

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	



US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:22
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 9 (Day 9)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '25 Jan 2021'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	26 Jan 2021 17:22:52

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Mitchell Stern (b) (4)	26 Jan 2021 17:22:52
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 10 (Day 10)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '26 Jan 2021'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	30 Jan 2021 00:46:24

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:46:24
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 11 (Day 11)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '27 Jan 2021'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	30 Jan 2021 00:49:27

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 12 (Day 12)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '28 Jan 2021'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	30 Jan 2021 00:49:27

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered missing code ND - Not Done.	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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Form: Symptom Log (12)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Moderate (Moderate)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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Form: Symptom Log (12)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 13 (Day 13)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '29 Jan 2021'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '98'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	30 Jan 2021 00:49:27

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Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '97.5' F	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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Form: Symptom Log (13)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	



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Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (13)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Simone Riley (b) (4)	30 Jan 2021 00:49:27
	(b) (4)	

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Form: Symptom Log (14)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 14 (Day 14)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Form: Symptom Log (14)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '30 Jan 2021'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	



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Form: Symptom Log (14)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '99'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	31 Jan 2021 15:31:42

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Form: Symptom Log (14)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '98.5' F	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	



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Form: Symptom Log (14)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Form: Symptom Log (14)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	31 Jan 2021 15:31:42
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 15 (Day 15)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '31 Jan 2021'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '97'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	01 Feb 2021 01:45:50

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '98.6' F	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

Nasal Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	01 Feb 2021 01:45:50
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Day 16 (Day 16)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '1 Feb 2021'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '98'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User entered '%'	System	02 Feb 2021 00:55:30

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '98.5' F	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Mild (Mild)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	

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Folder: Covid-19 Assessment 25 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 23:05:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:03
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'None (None)'	Oladunni Adeyiga (b) (4)	02 Feb 2021 00:55:30
	(b) (4)	



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Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '29 Jan 2021'	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '29 Jan 2021'	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

[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)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:01:44



US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:01:44

US3682211

Folder: Covid-19 Assessment 25 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 23:05:54

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:10:08
User entered '0'	System	02 Feb 2021 19:01:44

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	02 Feb 2021 19:02:01

US3682211

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 23:05:54

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 01:59:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 01:59:41
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	03 Feb 2021 01:59:41
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 19:02:01
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '31 Jan 2021' reason for change: New Information	(b) (4) (b) (4), (b) (6)	03 Feb 2021 01:59:41
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	02 Feb 2021 19:02:01

US3682211

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 23:05:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Feb 2021 01:59:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 01:59:41
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	03 Feb 2021 01:59:41
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 19:02:01
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01



**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:05:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:05:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:05:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:05:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:05:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:05:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01



**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:05:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:05:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:05:54**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:05:54**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:16
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:02:01

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:21:02



**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:21:02

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:38
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:21:02

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:38
User entered 'SICKD1'	System	30 Jan 2021 00:21:02

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '16:10'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered '29 Jan 2021 16:10'	System	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '62' in	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29
DataPoint set to visible.	System	30 Jan 2021 00:21:02



**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '110' lb	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29
DataPoint set to visible.	System	30 Jan 2021 00:21:02

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '81'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered 'bpm'	System	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '16'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered 'breaths/min'	System	12 Feb 2021 19:59:29



**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '103'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered 'mmHg'	System	12 Feb 2021 19:59:29

US3682211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:05:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 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)	15 Feb 2021 05:31:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	12 Feb 2021 20:02:05
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		12 Feb 2021 19:59:29
User entered '58'	(b) (4), (b) (6)	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48
User entered 'mmHg'	System	12 Feb 2021 19:59:29

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:48

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 20:02:52

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:28:56
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 20:02:52



US3682211

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 23:05:54

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:21:14

**US3682211**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 23:05:54**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:29:07
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	30 Jan 2021 00:21:14

US3682211

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 23:05:54

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Feb 2021 09:51:52
Query 'Data is required. Please complete.' answered with 'data entry error' (Site from System).	(b) (4), (b) (6)	30 Jan 2021 01:40:32
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Jan 2021 01:40:32
User entered empty; reason for change Data Entry Error	System	30 Jan 2021 01:40:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Jan 2021 01:40:10
	(b) (4), (b) (6)	30 Jan 2021 01:39:42

US3682211

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 23:05:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Jan 2021 01:40:10
User entered '29 Jan 2021'	(b) (4), (b) (6)	30 Jan 2021 01:39:42

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:56:56

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Mitchell Stern (b) (4)	16 Jan 2021 00:00:28
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Mitchell Stern (b) (4)	15 Jan 2021 23:55:16
User entered '11 Jan 2021'	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 01:56:56

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:56:56

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 01:56:56



US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:05:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Simone Riley (b) (4)	04 Feb 2021 19:15:37
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sandy MacNicoll (b) (4)	25 Jan 2021 21:07:08
User entered '15 Jan 2021'	(b) (4)	
	Christopher Blades (b) (4)	15 Jan 2021 21:48:16
	(b) (4)	

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:42:21

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	Christopher Blades (b) (4)	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:42:21

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:05:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Sandy MacNicoll (b) (4)	25 Jan 2021 21:07:08
User entered '15 Jan 2021'	(b) (4)	
	Christopher Blades (b) (4)	15 Jan 2021 21:48:16
	(b) (4)	

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:05:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4)	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 16:23:05
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4)	15 Jan 2021 21:48:16
	(b) (4)	

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 16:23:05
User entered 'Placebo (Placebo)'	Christopher Blades (b) (4)	15 Jan 2021 21:48:16



**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	Christopher Blades (b) (4)	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '1'	System	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'I'	System	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	15 Jan 2021 22:05:35
DataPoint set to visible.	System	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35



**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	15 Jan 2021 22:05:35
DataPoint set to visible.	System	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User accepted default value 'Pre-Dose (PREDOSE)'	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	Christopher Blades (b) (4)	15 Jan 2021 22:05:35

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:15:27
Comment added 'OL-1 was a split visit, ICF conducted 1/11/2021 and dosing administered on 1/15/2021. Please advise how to resolve query'.	(b) (4), (b) (6)	24 Feb 2021 18:43:49
Comment added 'OL-1 was a split visit, ICF conducted 1/11/2021 and dosing administered on 1/15/2021.'.	(b) (4), (b) (6)	12 Feb 2021 20:09:02
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Jan 2021 00:00:28
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 23:55:16
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:05:35
User entered '15 Jan 2021'	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '13:15'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '15 Jan 2021 13:15'	System	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '98.5' F	Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35



**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '69'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'bpm'	System	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '16'	Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'breaths/min'	System	15 Jan 2021 22:05:35

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '98'	(b) (4) Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'mmHg'	System	15 Jan 2021 22:05:35

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:05:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 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 Jan 2021 10:17:16
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS ' (Site from System).	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:06:18
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		15 Jan 2021 22:05:35
User entered '39'	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:05:35



**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'mmHg'	System	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered missing code ND - Not Done.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:05:54**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	15 Jan 2021 22:05:35
DataPoint set to visible.	System	15 Jan 2021 21:48:16

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User accepted default value 'Post-Dose (POSTDOSE)'	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:15:35
Comment added "OL-1 was a split visit, ICF conducted 1/11/2021 and dosing administered on 1/15/2021, date correct as entered.'	(b) (4), (b) (6)	12 Feb 2021 20:11:00
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Jan 2021 00:00:28
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 23:55:16
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 22:05:35
User entered '15 Jan 2021'	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '14:01'	Christopher Blades (b) (4)	15 Jan 2021 22:05:35



**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '15 Jan 2021 14:01'	System	15 Jan 2021 22:05:35

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '98.4' F	Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Oral (Oral)'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '62'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'bpm'	System	15 Jan 2021 22:05:35

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '16'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'breaths/min'	System	15 Jan 2021 22:05:35



US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:05:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '102'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'mmHg'	System	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '68'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'mmHg'	System	15 Jan 2021 22:05:35

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 21:48:28

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:05:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System (b) (4)	16 Jan 2021 00:00:28
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 23:55:16
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 21:57:39
User entered '11 Jan 2021' reason for change: New Information	Christopher Blades (b) (4)	15 Jan 2021 21:57:39
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System (b) (4)	15 Jan 2021 21:55:57
User entered '15 Jan 2021' reason for change: New Information	Christopher Blades (b) (4)	15 Jan 2021 21:55:57
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 21:48:46
User entered '11 Jan 2021' reason for change: Data Entry Error	Christopher Blades (b) (4)	15 Jan 2021 21:48:46
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 21:48:28
User entered '15 Jan 2021'	Christopher Blades (b) (4)	15 Jan 2021 21:48:28

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	Christopher Blades (b) (4)	15 Jan 2021 21:49:03

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 21:49:03



US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered empty.	Christopher Blades (b) (4)	15 Jan 2021 21:49:03

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'mRNA-1273'	System	15 Jan 2021 21:49:03
DataPoint set to visible.	System	15 Jan 2021 21:48:16

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 05:23:52
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Decision visit and open label day 1 were performed separately. ' (Site from System).	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 21:54:44
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 21:49:03
User entered '15 Jan 2021'	Christopher Blades (b) (4) (b) (4)	15 Jan 2021 21:49:03

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '13:29'	(b) (4) Christopher Blades (b) (4)	15 Jan 2021 21:49:03

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '15 Jan 2021 13:29'	System	15 Jan 2021 21:49:03

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Left Arm (LEFT ARM)'	Christopher Blades (b) (4)	15 Jan 2021 21:49:03

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'ONCE'	System	15 Jan 2021 21:49:03

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'INTRAMUSCULAR'	System	15 Jan 2021 21:49:03



**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:57:07

US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:05:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	16 Jan 2021 00:00:28
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	16 Jan 2021 00:00:28
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Jan 2021 23:55:16
User entered '11 Jan 2021'	(b) (4), (b) (6)	12 Jan 2021 01:57:07

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '16:36'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:57:07

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '11 Jan 2021 16:36'	System	12 Jan 2021 01:57:07

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:57:19

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:05:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:57:19

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:05:54**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered '16:41'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:57:19

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:05:54**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '11 Jan 2021 16:41'	System	12 Jan 2021 01:57:19



US3682211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:05:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	25 Jan 2021 17:27:51

**US3682211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'I'	System	25 Jan 2021 17:27:51

**US3682211**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	26 Jan 2021 01:50:45

**US3682211**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered '25 Jan 2021'	(b) (4) Mitchell Stern (b) (4)	26 Jan 2021 01:50:45

**US3682211**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4)	26 Jan 2021 01:50:45

**US3682211**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	26 Jan 2021 01:50:45

**US3682211**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	05 Mar 2021 23:19:10
User entered 'Yes (Y)'	(b) (4) Mitchell Stern (b) (4)	26 Jan 2021 01:50:52

**US3682211**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'I'	System	26 Jan 2021 01:50:52



**US3682211**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '1'	System	26 Jan 2021 01:50:52
DataPoint set to visible.	System	26 Jan 2021 01:50:52

**US3682211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Yes (Y)'	Jesse Clark (b) (4)	27 Feb 2021 00:48:32

**US3682211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '26 Feb 2021'	Jesse Clark (b) (4)	27 Feb 2021 00:48:32

**US3682211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Clinic (Clinic)'	Jesse Clark (b) (4)	27 Feb 2021 00:48:32

**US3682211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'OLD29'	System	27 Feb 2021 00:48:32

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User accepted default value 'Pre-Dose (PREDOSE)'	Jesse Clark (b) (4) (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Yes (Y)'	Jesse Clark (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '26 Feb 2021'	Jesse Clark (b) (4)	27 Feb 2021 00:50:09



**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '16:35'	Jesse Clark (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered '26 Feb 2021 16:35'	System	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '97.0' F	Jesse Clark (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Oral (Oral)'	(b) (4) Jesse Clark (b) (4) (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '80'	Jesse Clark (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'bpm'	System	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '16'	Jesse Clark (b) (4)	27 Feb 2021 00:50:09



**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'breaths/min'	System	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '106'	Jesse Clark (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'mmHg'	System	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '70'	Jesse Clark (b) (4)	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'mmHg'	System	27 Feb 2021 00:50:09

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User accepted default value 'Post-Dose (POSTDOSE)'	Jesse Clark (b) (4) (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'No (N)'	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15



**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15



**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:50:15

**US3682211**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Yes (Y)'	Jesse Clark (b) (4)	27 Feb 2021 00:48:42

**US3682211**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '26 Feb 2021'	Jesse Clark (b) (4)	27 Feb 2021 00:48:42

**US3682211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'No (N)'	Jesse Clark (b) (4)	27 Feb 2021 00:49:12



US3682211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User closed query 'Per CDM: Reason for treatment not given is Participant declined due to Adverse Event; however, there is no Adverse event recorded with Action taken= Investigational product withdrawn. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:08:30
Query 'Per CDM: Reason for treatment not given is Participant declined due to Adverse Event; however, there is no Adverse event recorded with Action taken= Investigational product withdrawn. Please review and reconcile. ' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:14:54
User opened query 'Per CDM: Reason for treatment not given is Participant declined due to Adverse Event; however, there is no Adverse event recorded with Action taken= Investigational product withdrawn. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 11:50:16
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Jesse Clark (b) (4)	27 Feb 2021 00:49:12

US3682211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Pt. refused second dose' reason for change: Data Entry Error	(b) (4)	
	Sandy MacNicoll (b) (4)	25 Mar 2021 17:57:14
User entered empty.	(b) (4)	
	Jesse Clark (b) (4)	27 Feb 2021 00:49:12
	(b) (4)	

**US3682211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:49:12
DataPoint set to visible.	System	26 Jan 2021 01:50:52

US3682211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:05:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:49:12

**US3682211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:49:12

**US3682211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:49:12

**US3682211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	Jesse Clark (b) (4)	27 Feb 2021 00:49:12

**US3682211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:49:12



**US3682211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:05:54**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered empty.	System	27 Feb 2021 00:49:12

**US3682211**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Yes (Y)'	Jesse Clark (b) (4)	27 Feb 2021 00:50:27

**US3682211**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'I'	System	27 Feb 2021 00:50:27

**US3682211**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	08 Mar 2021 22:55:29

**US3682211**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered '8 Mar 2021'	(b) (4) Mitchell Stern (b) (4)	08 Mar 2021 22:55:29

**US3682211**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mitchell Stern (b) (4)	08 Mar 2021 22:55:29

**US3682211**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:05:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered empty.	(b) (4) Mitchell Stern (b) (4) (b) (4)	08 Mar 2021 22:55:29

**US3682211**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User signature succeeded.	Jesse Clark (b) (4)	25 Mar 2021 18:34:17
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	08 Mar 2021 22:55:35



**US3682211**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:05:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:10:53
User entered 'I'	System	08 Mar 2021 22:55:35

**US3682211**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Christopher Blades (b) (4)	08 Apr 2021 20:47:31
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '8 Apr 2021'	Christopher Blades (b) (4)	08 Apr 2021 20:47:31
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered 'Clinic (Clinic)'	Christopher Blades (b) (4)	08 Apr 2021 20:47:31
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:05:54**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	08 Apr 2021 20:47:31

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '8 Apr 2021'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '12:50'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	



**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 12:50'	System	08 Apr 2021 20:48:04

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '98.5' F	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered 'Oral (Oral)'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '73'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Apr 2021 20:48:04

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '16'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Apr 2021 20:48:04



**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '99'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 20:48:04

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '62'	Christopher Blades (b) (4)	08 Apr 2021 20:48:04
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:05:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 20:48:04

**US3682211**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Christopher Blades (b) (4)	08 Apr 2021 20:48:11
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:05:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
	(b) (4)	
User entered '8 Apr 2021'	Christopher Blades (b) (4)	08 Apr 2021 20:48:11
	(b) (4)	

**US3682211**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:40:44

**US3682211**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
User entered '8 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:40:44



**US3682211**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
User entered '13:06'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:40:44

**US3682211**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:05:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 13:06'	System	08 Apr 2021 23:40:44

US3682211

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 23:05:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:32:21
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 96, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:07:54
Query 'Per DM CLR: Per Safety Follow Up Diary Day 96, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'AE page updated accordingly' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	30 Mar 2021 16:51:28
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 96, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 07:50:27
User signature succeeded.	Jesse Clark (b) (4) (b) (4)	19 Mar 2021 21:21:01
User entered 'Yes (Y)' reason for change: New Information	Mitchell Stern (b) (4) (b) (4)	18 Feb 2021 18:36:26
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 18:29:59

US3682211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:54

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:27:15
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'pt denied headaches lasting longer than 48 hours.' (Site from DM).	Mitchell Stern (b) (4)	29 Mar 2021 23:57:51
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 14:58:31
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 18:41:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 18:41:54
Data point term sent to Coder	System	18 Feb 2021 18:40:44
User entered 'Intermittent Headache'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:40:19
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' answered with 'AE does not meet criteria for solicited event ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 18:32:34
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Mar 2021 18:32:11
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:30:44
User entered 'Yes (Y)' reason for change: New Information	Mitchell Stern (b) (4)	18 Feb 2021 18:47:31
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '16 Jan 2021'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	



**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Feb 2021 18:41:01
User entered '18:00' reason for change: New Information	Mitchell Stern (b) (4)	18 Feb 2021 18:41:01
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Feb 2021 18:40:32
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Jan 2021 18:00'	System	18 Feb 2021 18:41:01
User entered empty.	System	18 Feb 2021 18:40:32

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:27:19
Query 'Per MM, please provide the end date.' answered with 'Intermittent headaches were continued as of safety call on 3/19/21' (Site from DM).	Mitchell Stern (b) (4)	29 Mar 2021 23:59:25
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4)	29 Mar 2021 14:58:49
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
User entered 'Yes (Y)'	(b) (4)	
	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Feb 2021 18:40:32

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	



**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

US3682211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:05:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	



**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'Related (RELATED)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'None (NONE)'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered 'I'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	



**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Mitchell Stern (b) (4)	18 Feb 2021 18:40:32

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	18 Feb 2021 18:40:32
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	19 Mar 2021 21:21:01
User entered 'Pt previously evaluated for illness symptoms, including headache. Headache reported as continued and intermittent. Pt denied use of medication and said that the headaches self-resolve in 30 minutes to an hour.'	(b) (4) Mitchell Stern (b) (4)	18 Feb 2021 18:40:32

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Feb 2021 18:40:32

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:05:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Feb 2021 18:40:32

US3682211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Mar 2021 16:48:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 16:48:55
Data point term sent to Coder	System	30 Mar 2021 16:47:27
User entered 'COVID-like illness'	Mitchell Stern (b) (4) (b) (4)	30 Mar 2021 16:47:11

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Yes (Y)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	



**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '17 Jan 2021'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:47:11

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '1 Feb 2021'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:47:11



**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'No (N)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	



**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

US3682211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:54

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
User closed query 'Per CDM: Action taken with investigational product is recorded as 'Investigational Product Withdrawn' however, the corresponding Dosing discontinuation is not completed. Please confirm and update. Else clarify. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 08:21:33
Query 'Per CDM: Action taken with investigational product is recorded as 'Investigational Product Withdrawn' however, the corresponding Dosing discontinuation is not completed. Please confirm and update. Else clarify. Thank you. ' answered with 'The investigational product was withdrawn during part B of the study. Thus, the dosing discontinuation form is not applicable.' (Site from DM).	Mitchell Stern (b) (4) (b) (4)	13 Apr 2021 17:09:34
User opened query 'Per CDM: Action taken with investigational product is recorded as 'Investigational Product Withdrawn' however, the corresponding Dosing discontinuation is not completed. Please confirm and update. Else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:04:44
User closed query 'Per CDM: Action taken with investigational product = Dose Delayed; however, the Exposure form on OL-D29 indicates that the study treatment was not given. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:01:36
Query 'Per CDM: Action taken with investigational product = Dose Delayed; however, the Exposure form on OL-D29 indicates that the study treatment was not given. Please review and reconcile. ' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:14:42
Signature has been broken.	(b) (4), (b) (6)	06 Apr 2021 17:12:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 17:12:35

US3682211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Action taken with investigational product = Dose Delayed; however, the Exposure form on OL-D29 indicates that the study treatment was not given. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 11:52:50
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4) Mitchell Stern (b) (4)	30 Mar 2021 16:47:11



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:05:54

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	30 Mar 2021 16:47:17
User entered '1' reason for change: Data Entry Error	Mitchell Stern (b) (4)	30 Mar 2021 16:47:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	30 Mar 2021 16:47:11
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered '0'	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mitchell Stern (b) (4)	30 Mar 2021 16:47:11

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
	(b) (4)	
User entered empty.	Mitchell Stern (b) (4)	30 Mar 2021 16:47:11
	(b) (4)	

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Mar 2021 16:47:11

**US3682211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:05:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 16:47:11



**US3682211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 23:05:54**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:30:53

US3682211

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 23:05:54**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jesse Clark (b) (4)	01 Apr 2021 21:05:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:08:35

US3682211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:05:54

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:40:02
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 14:59:39
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 23:39:33
Query 'Data is required. Please complete.' answered with 'Error. Pt. received both doses under part A, unblinded and received first active first active dose, refused second dose' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 20:06:06
User opened query 'Data is required. Please complete.' (Site from System).	Sandy MacNicoll (b) (4)	25 Mar 2021 17:37:35
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '26 Feb 2021'	System	25 Mar 2021 17:32:18
	Sandy MacNicoll (b) (4)	25 Mar 2021 17:32:18
	(b) (4)	
	Sandy MacNicoll (b) (4)	02 Mar 2021 18:26:37
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:05:54

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:40:02
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	09 Apr 2021 14:59:41
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	07 Apr 2021 23:39:33
Query 'Data is required. Please complete.' answered with 'N/a' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 20:06:06
User opened query 'Data is required. Please complete.' (Site from System).	Sandy MacNicoll (b) (4)	25 Mar 2021 17:38:11
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Other (OTHER)'	System	25 Mar 2021 17:37:41
	Sandy MacNicoll (b) (4)	25 Mar 2021 17:37:41
	(b) (4)	
	Sandy MacNicoll (b) (4)	02 Mar 2021 18:26:37
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:05:54

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)	29 Apr 2021 03:40:02
User signature succeeded.	Jesse Clark (b) (4)	15 Apr 2021 21:28:57
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:39:33
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	25 Mar 2021 20:06:06
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	25 Mar 2021 17:37:41
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	25 Mar 2021 17:32:18
User entered empty; reason for change Data Entry Error	Sandy MacNicoll (b) (4) (b) (4)	25 Mar 2021 17:32:18
User entered 'Pt. refused 2nd injection of mRNA-1273 due to concerns of increased possible side effects'	Sandy MacNicoll (b) (4) (b) (4)	02 Mar 2021 18:26:37