

US3862286 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:34:47

All time stamps listed in this document are displayed in GMT

US3862286

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Participant ID

US3862286

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

US3862286

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 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) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 16:00:16

Generated On: 12 Aug 2021 13:34:47

Condition	MELANOMA RIGHT HIP STAGE 1
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 16:00:16

Generated On: 12 Aug 2021 13:34:47

Condition	PSORIASIS INTERMITTENT
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Start Year (derived)	1976
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 16:00:16

Generated On: 12 Aug 2021 13:34:47

Condition	HYPOTHYROIDISM
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)	

US3862286

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 16:00:16

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 16:00:16

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 16:00:16

Generated On: 12 Aug 2021 13:34:47

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1976
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 1976
Start Year (derived)	1976
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 16:00:16

Generated On: 12 Aug 2021 13:34:47

Condition	BASAL CELL CARCINOMA SUPRASTERNAL NOTCH
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:46 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:46
Height (<i>xxx.x</i>)	185.0 cm
Weight (<i>xxx.x</i>)	163.8 lb
BMI (<i>xxx.x</i>)	21.75443 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:18:43

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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) 13 Feb 2021 01:18:43

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

What was the date of randomization? (dd MMM yyyy) 16 OCT 2020

What was the participant's randomization number? 116284

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) 13 Feb 2021 01:18:43

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Height	
Weight	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Height	
Weight	
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)	16 OCT 2020
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 08:46
Temperature (xxx.x)	097.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	054 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	066 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Height	
Weight	
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)	16 OCT 2020
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 10:57
Temperature (xxx.x)	096.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	050 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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) 16 OCT 2020

What was the treatment time? (00:00-23:59) 10:26 (24 HR)

Treatment Date and Time (derived) 16 OCT 2020 10:26

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) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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

Collection date (dd MMM yyyy)	16 OCT 2020
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Collection time (00:00-23:59)	09:25 (24 HR)
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Collection date and time (derived)	16 OCT 2020 09:25
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US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	16 OCT 2020 09:20
Nasopharyngeal Swab 2	No		

US3862286

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 10:58

PC Open Date & Time

16 OCT 2020 10:46

PC Close Date & Time

16 OCT 2020 13:16

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 08:06

PC Open Date & Time

16 OCT 2020 14:11

PC Close Date & Time

17 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 17:36

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

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

95.9 °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

18 OCT 2020 18:24

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 17:50

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

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

98.1 °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

20 OCT 2020 12:10

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

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

22 OCT 2020 06:45

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

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

98.3 °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

22 OCT 2020 12:44

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 10:58

PC Open Date & Time

16 OCT 2020 10:46

PC Close Date & Time

16 OCT 2020 13:16

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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

16 OCT 2020 18:08

PC Open Date & Time

16 OCT 2020 14:11

PC Close Date & Time

17 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

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

17 OCT 2020 17:37

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

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

18 OCT 2020 18:24

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

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

19 OCT 2020 17:50

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

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

20 OCT 2020 12:10

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 06:44

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

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

22 OCT 2020 12:44

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 10:59
PC Open Date & Time	16 OCT 2020 10:46
PC Close Date & Time	16 OCT 2020 13:16

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 18:09
PC Open Date & Time	16 OCT 2020 14:11
PC Close Date & Time	17 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

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: 12 Aug 2021 13:34:47

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 17:37
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

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 ☒

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

		Yes <input type="checkbox"/>
PC Time stamp	18 OCT 2020 18:24	
PC Open Date & Time	18 OCT 2020 12:00	
PC Close Date & Time	19 OCT 2020 11:59	

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

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 ☒

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 17:51
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

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 ☒

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 06:44
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

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 ☒

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 12:44
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3862286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:18:12

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:12

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:18:42

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:12

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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)	18 NOV 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 15:38
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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.

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☒
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3862286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

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

Collection date (dd MMM yyyy)	18 NOV 2020
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Collection time (00:00-23:59)	15:48 (24 HR)
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Collection date and time (derived)	18 NOV 2020 15:48
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US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Collection date (dd MMM yyyy)			18 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	15:44	18 NOV 2020 15:44

US3862286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:37:48

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:37:42

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:18:42

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:42

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:18:42

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:42

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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 _____

US3862286

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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)	

US3862286

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

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.

US3862286

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3862286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:18:43

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

Date and time of submission

Patient Cloud Open Date & Time	20 DEC 2020 00:01
--	-------------------

Patient Cloud Close Date & Time	24 DEC 2020 23:59
---	-------------------

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☒

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 12:01:50

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 06:36:51

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 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	20 JAN 2021 18:01:31
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

24 JAN 2021 08:24:33

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 10:52:01

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 FEB 2021 07:53:44
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 09:15:06
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

25 FEB 2021 00:01:33

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

02 MAR 2021 12:01:05

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

09 MAR 2021 12:05:22

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

16 MAR 2021 12:30:48

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

23 MAR 2021 12:17:48

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

28 MAR 2021 07:43:46

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

04 APR 2021 11:16:37

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

12 APR 2021 07:14:53

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

19 APR 2021 06:59:21

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

25 APR 2021 07:40:24

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 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	02 MAY 2021 19:06:41
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐
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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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°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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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°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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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="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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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="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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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°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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 <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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐
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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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°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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2022 23:59

US3862286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:34:47

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 12:01:15

US3862286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:37:48

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:37:48

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 18:40:17

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:40:17

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 30 Apr 2021 16:49:42

Generated On: 12 Aug 2021 13:34:47

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

Visit date (dd MMM yyyy)	30 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	VISIT4
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US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Apr 2021 16:49:42

Generated On: 12 Aug 2021 13:34:47

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3862286

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Apr 2021 16:49:42

Generated On: 12 Aug 2021 13:34:47

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.

US3862286

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Apr 2021 16:49:42

Generated On: 12 Aug 2021 13:34:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 APR 2021

Collection time (00:00-23:59)

10:59 (24 HR)

Collection date and time (derived)

30 APR 2021 10:59

US3862286

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:46:39

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 14:45:20

Generated On: 12 Aug 2021 13:34:47

Date of Contact	2 NOV 2020
Time of Contact	14:30
Date and Time of Contact (derived)	2 NOV 2020 14:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input 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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US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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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US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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	2 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.5 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"/>

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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	3 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.6 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

Symptom Day

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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	4 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.8 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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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

Symptom Day

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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	5 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" 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 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

	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	6 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	100.3 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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EAB) (1725)

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 21:45:50

Generated On: 12 Aug 2021 13:34:47

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 02 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 14:45:20

Generated On: 12 Aug 2021 13:34:47

Date of Visit	2 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	2 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 14:45:20

Generated On: 12 Aug 2021 13:34:47

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 14:45:20

Generated On: 12 Aug 2021 13:34:47

Date of Contact	16 DEC 2020
Time of Contact	15:10
Date and Time of Contact (derived)	16 DEC 2020 15:10
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input 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>

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	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	09 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 16 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Symptom Day

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

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Form: Symptom Log (2)

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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	10 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:04:21

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input 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 16 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 16 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

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Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 (5)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 16 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 16 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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 16 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.0 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 16 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" 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 16 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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 16 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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 ☐

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	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 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 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 16 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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 16 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

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"/>

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 14:45:20

Generated On: 12 Aug 2021 13:34:47

Date of Visit	16 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	16 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	4 NOV 2020
Day 5	Yes	6 NOV 2020
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)	

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 DEC 2020
Day 5	Yes	20 DEC 2020
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)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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	SICKD1

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 14:20
Height (xxx.x)	185 cm
Weight (xxx.x)	163.8 lb
Temperature (xxx.x)	99.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3862286

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 NOV 2020

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

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

Visit date (dd MMM yyyy)	16 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	SICKD1
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US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 DEC 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	16 DEC 2020 15:20
Height (xxx.x)	185.0 cm
Weight (xxx.x)	163.8 lb
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 DEC 2020

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

US3862286

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 DEC 2020

US3862286

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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 _____

US3862286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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)	

US3862286

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

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

Generated On: 12 Aug 2021 13:34:47

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3862286

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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 _____

US3862286

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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)	

US3862286

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

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.

US3862286

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:34:47

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3862286

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

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

Visit date (dd MMM yyyy)	10 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	UNBLND_DECIDE
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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

Date of updated informed consent (<i>dd MMM yyyy</i>)	10 FEB 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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	17 DEC 2020
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3862286

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:45:30

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

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

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)	10 FEB 2021
Time of assessment (00:00-23:59)	08:31 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 08:31
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3862286

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

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)	10 FEB 2021
Time of assessment (00:00-23:59)	11:23 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 11:23
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3862286

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 FEB 2021

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

US3862286

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

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) 10 FEB 2021

What was the treatment time? (00:00-23:59) 10:53 (24 HR)

Treatment Date and Time (derived) 10 FEB 2021 10:53

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

US3862286

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 10 FEB 2021

Collection time (00:00-23:59) 08:39 (24 HR)

Collection date and time (derived) 10 FEB 2021 08:39

US3862286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 FEB 2021
Collection time (00:00 - 23:59)	08:36
Collection Date and Time (derived)	10 FEB 2021 08:36

US3862286

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3862286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:45:30

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

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

Visit date (dd MMM yyyy)	22 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 11:28
Temperature (xxx.x)	097.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	050 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	064 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862286

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3862286

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:45:22

Generated On: 12 Aug 2021 13:34:47

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 22 MAR 2021

Collection time (00:00-23:59) 11:45 (24 HR)

Collection date and time (derived) 22 MAR 2021 11:45

US3862286

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:23:41

Generated On: 12 Aug 2021 13:34:47

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 15:23:40

Generated On: 12 Aug 2021 13:34:47

AEID	
Adverse event	VIRAL LIKE ILLNESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Mar 2021 15:23:40

Generated On: 12 Aug 2021 13:34:47

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

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Mar 2021 15:23:40

Generated On: 12 Aug 2021 13:34:47

AEID

Adverse event

VIRAL UPPER RESPIRATORY
SYMPTOMS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

9 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Mar 2021 15:23:40

Generated On: 12 Aug 2021 13:34:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:45:20

Generated On: 12 Aug 2021 13:34:47

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

Yes ☒

No ☐

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

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify SPRAY

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR GENERAL HEALTH

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1985	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication MELANOMA

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR GENERAL

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1985
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication VIRAL LIKE ILLNESS

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication VIRAL LIKE ILLNESS

Dose per administration 400

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 4-6 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication WALGREENS COLD AND FLU LIQUID

Prophylaxis Yes ☐
No ☒

Indication VIRAL LIKE ILLNESS

Dose per administration 30

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	5 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication VIRAL LIKE ILLNESS

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		6 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication AZITHROMYCIN Z-PACK

Prophylaxis Yes ☐
No ☒

Indication VIRAL LIKE ILLNESS

Dose per administration 250

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

Name of Medication AZITHROMYCIN Z-PACK

Prophylaxis Yes ☐
No ☒

Indication VIRAL LIKE ILLNESS

Dose per administration 250

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 02 Apr 2021 14:45:19

Generated On: 12 Aug 2021 13:34:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862286

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:45:20

Generated On: 12 Aug 2021 13:34:47

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 12 Aug 2021 13:34:47

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 02 Apr 2021 14:45:21

Generated On: 12 Aug 2021 13:34:47

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

Case Report Form

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

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 02 Apr 2021 14:45:21

Generated On: 12 Aug 2021 13:34:47

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	16 DEC 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	True
Other, specify	ILLNESS VISIT
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	True
Presumption / confirmed COVID-19	False
Symptoms of COVID-19	True
Sponsor hold due to COVID-19	False
Participant decision	False

US3862286

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Apr 2021 14:04:21

Generated On: 12 Aug 2021 13:34:47

Date of dosing discontinuation (dd MMM yyyy) 16 OCT 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

AE# 01

US3862286

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:34:47

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

US3862286 (Prod: Baylor College of Medicine)

US3862286

Form: Participant Creation

Generated On: 12 Aug 2021 13:34:47

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'US3862286'	RWS_ENDPOINT	16 Oct 2020 13:58:38
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:45

US3862286

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 13:58:39

US3862286

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:45

US3862286

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'SCRN'	System	16 Oct 2020 15:01:45

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered (b) (6) 1966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 13:58:40

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '54'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'YEARS'	System	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '54'	System	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Male (M)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

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Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:34:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:20

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Oct 2020'	System	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2020'	System	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Amendment 4 (4)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:53

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 13:58:39

US3862286

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:34:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '1'	System	16 Oct 2020 15:01:58

US3862286

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:34:47

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:01:58

US3862286

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:34:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:30

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 12:57:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Mar 2021 12:57:16
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 16:00:16
Data point term sent to Coder	System	22 Mar 2021 17:23:40
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 17:22:55
Signature has been broken.		22 Mar 2021 17:22:55
User entered 'MELANOMA RIGHT HIP STAGE 1' reason for change: New Information		22 Mar 2021 17:22:55
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 01:18:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 12:02:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 12:02:32
Data point term sent to Coder	System	16 Oct 2020 15:46:16
User entered 'Melanoma Stage 1'	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 2011'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 2011'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2011'	System	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2011'	System	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2011'	System	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2011'	System	16 Oct 2020 15:46:11

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:56:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:56:03
Data point term sent to Coder	System	16 Oct 2020 15:47:17
User entered 'Psoriasis intermittent'	Trent Davis (b) (4)	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 1976'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 1976'	System	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '1976'	System	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:46:43

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:48:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 15:48:34
Data point term sent to Coder	System	16 Oct 2020 15:47:16
User entered 'Hypothyroidism'	Trent Davis (b) (4)	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 2015'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2015'	System	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2015'	System	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:47:07

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Thyroid neoplasms benign, PT: Benign neoplasm of thyroid gland, LLT: Benign thyroid nodule - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 15:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 15:55:35
Data point term sent to Coder	System	19 Oct 2020 15:54:31
User closed query 'For coding purposes, please split BENIGN THYROID NODULE S/P LEFT THYROIDECTOMY into separate entries' (Site from System).	System	19 Oct 2020 15:54:23
Query 'For coding purposes, please split BENIGN THYROID NODULE S/P LEFT THYROIDECTOMY into separate entries' answered with 'data corrected' (Site from System).	Trent Davis (b) (4)	19 Oct 2020 15:54:23
User entered 'BENIGN THYROID NODULE' reason for change: Data Entry Error	Trent Davis (b) (4)	19 Oct 2020 15:54:15
User opened query 'For coding purposes, please split BENIGN THYROID NODULE S/P LEFT THYROIDECTOMY into separate entries' (Site from System).	Coder Import (b) (4)	18 Oct 2020 15:06:18
Data point term sent to Coder	System	16 Oct 2020 15:49:20
User entered 'Benign Thyroid nodule s/p left thyroidectomy'	Trent Davis (b) (4)	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 2015'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 2015'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2015'	System	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2015'	System	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2015'	System	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2015'	System	16 Oct 2020 15:48:28

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:30:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 16:30:28
Data point term sent to Coder	System	19 Oct 2020 15:55:31
User entered 'S/P LEFT THYROIDECTOMY'	Trent Davis (b) (4)	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 2015'	(b) (4) Trent Davis (b) (4)	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 2015'	(b) (4) Trent Davis (b) (4)	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2015'	System	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2015'	System	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2015'	System	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2015'	System	19 Oct 2020 15:54:52

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:51:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:51:35
Data point term sent to Coder	System	01 Dec 2020 16:49:33
User entered 'Seasonal Allergies'	Trent Davis (b) (4)	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'un UNK 1976'	(b) (4) Trent Davis (b) (4)	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 1976'	System	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '1976'	System	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	01 Dec 2020 16:49:05

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 16:00:16
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	(b) (4)	23 Mar 2021 05:14:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 05:14:30
Data point term sent to Coder	System	22 Mar 2021 17:25:45
User entered 'BASAL CELL CARCINOMA SUPRASTERNAL NOTCH'	(b) (4), (b) (6)	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 16:00:16
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 16:00:16
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 16:00:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 16:00:16
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 16:00:16
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2014'	System	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2014'	System	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'Jan 2014'	System	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '2014'	System	22 Mar 2021 17:25:09

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '08:46'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '16 Oct 2020 08:46'	System	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '185.0' cm	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:45:04
DataPoint set to visible.	(b) (4) System	16 Oct 2020 15:01:58

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '163.8' lb	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:45:04
DataPoint set to visible.	(b) (4) System	16 Oct 2020 15:01:58

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered '21.75443'	System	16 Oct 2020 15:45:04
DataPoint set to visible.	System	16 Oct 2020 15:01:58

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered 'kg/m2'	System	16 Oct 2020 15:45:04
DataPoint set to visible.	System	16 Oct 2020 15:01:58

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:47:15
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:09
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 15:45:04
User entered empty.	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:47:17
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:12
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 15:45:04
User entered empty.	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:47:19
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:15
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 15:45:04
User entered empty.	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:47:21
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 15:45:04
User entered empty.	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 11:47:24
Query 'Data is required. Please provide.' answered with 'nd' (Site from System).	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:22
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Oct 2020 15:45:04
User entered empty.	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User entered empty.	System	16 Oct 2020 15:45:04

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40

US3862286

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40

US3862286

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:26

US3862286

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:26

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

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 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'I'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:34:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 03:42:40
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:44:18

US3862286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:42

US3862286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:42

US3862286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:42

US3862286

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'VISIT1'	System	16 Oct 2020 15:02:42

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 14:48:31

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '116284'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	16 Oct 2020 14:48:31

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '>=18 and <65 years and not at risk (1)'	(b) (4)	16 Oct 2020 14:48:31
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:51

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 15:02:51
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:51

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:51

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:51

US3862286

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:34:47

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 15:02:51
DataPoint set to visible.	(b) (4) System	16 Oct 2020 15:01:53

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '08:46'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '16 Oct 2020 08:46'	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '097.8' F	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Other (Other)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'temporal'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '054'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'bpm'	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '012'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'breaths/min'	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '108'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'mmHg'	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '066'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'mmHg'	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:54:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:54:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4)	16 Oct 2020 18:54:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 15:43:22
User entered empty.	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	16 Oct 2020 18:54:49
User entered empty.	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '10:57' reason for change: Data Entry Error	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 18:54:49
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '16 Oct 2020 10:57'	System	16 Oct 2020 18:54:49
User entered empty.	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 05:54:15
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Trent Davis (b) (4) (b) (4)	16 Oct 2020 18:55:08
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Oct 2020 18:54:49
User entered '096.7' F reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	16 Oct 2020 18:54:49
User entered empty.	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	16 Oct 2020 18:54:49
User entered empty.	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '050' reason for change: Data Entry Error	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 18:54:49
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'bpm'	System	16 Oct 2020 18:54:49
User entered empty.	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '012' reason for change: Data Entry Error	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 18:54:49
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'breaths/min'	System	16 Oct 2020 18:54:49
User entered empty.	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '112' reason for change: Data Entry Error	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 18:54:49
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'mmHg'	System	16 Oct 2020 18:54:49
User entered empty.	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '073' reason for change: Data Entry Error	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 18:54:49
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	16 Oct 2020 15:43:22
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'mmHg'	System	16 Oct 2020 18:54:49
User entered empty.	System	16 Oct 2020 15:43:22

US3862286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:36

US3862286

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:36

US3862286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:38:21

US3862286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:38:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:38:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 15:38:21

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:38:21
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '10:26'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:38:21

US3862286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '16 Oct 2020 10:26'	System	16 Oct 2020 15:38:21

US3862286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:38:21

US3862286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'ONCE'	System	16 Oct 2020 15:38:21

US3862286

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 15:38:21

US3862286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	Trent Davis (b) (4)	16 Oct 2020 15:40:55

US3862286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	Trent Davis (b) (4)	16 Oct 2020 15:40:55

US3862286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '09:25'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:40:55
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '16 Oct 2020 09:25'	System	16 Oct 2020 15:40:55

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:34:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '16 Oct 2020'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:42:16
	(b) (4)	

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:42:16

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:42:16

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '09:20'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:42:16

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '16 Oct 2020 09:20'	System	16 Oct 2020 15:42:16

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	16 Oct 2020 15:42:16

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:42:16

US3862286

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Oct 2020 15:42:16

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	16 Oct 2020 15:42:16

US3862286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 15:02:57

US3862286

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '1'	System	16 Oct 2020 15:02:57

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:57:59', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '88495edc-bdfd-4942-a1cf-30c176995728' User entered 'Yes (Y)'	System	16 Oct 2020 15:58:37
	System	16 Oct 2020 15:58:37

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:06', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '88495edc-bdfd-4942-a1cf-30c176995728' User entered '96.7'	System	16 Oct 2020 15:58:37
	System	16 Oct 2020 15:58:37

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:11', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '88495edc-bdfd-4942-a1cf-30c176995728' User entered 'No (N)'	System	16 Oct 2020 15:58:37
	System	16 Oct 2020 15:58:37

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:31', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '88495edc-bdfd-4942-a1cf-30c176995728' User entered '16 Oct 2020 10:58'	System	16 Oct 2020 15:58:37
	System	16 Oct 2020 15:58:37

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 10:46'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 13:16'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T08:05:56', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b387f192-b623-4dff-bcca-754099201be1' User entered 'Yes (Y)'	System	17 Oct 2020 13:06:12
	System	17 Oct 2020 13:06:12

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T08:06:02', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b387f192-b623-4dff-bcca-754099201be1' User entered '97.6'	System	17 Oct 2020 13:06:12
	System	17 Oct 2020 13:06:12

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T08:06:07', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b387f192-b623-4dff-bcca-754099201be1' User entered 'No (N)'	System	17 Oct 2020 13:06:12
	System	17 Oct 2020 13:06:12

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T08:06:10', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b387f192-b623-4dff-bcca-754099201be1' User entered '17 Oct 2020 08:06'	System	17 Oct 2020 13:06:12
	System	17 Oct 2020 13:06:12

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 14:11'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 2'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:36:33', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c9ff9af9-2cf6-4fe5-aa64-6dcae75af98a' User entered 'Yes (Y)'	System	17 Oct 2020 22:36:46
	System	17 Oct 2020 22:36:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:36:37', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c9ff9af9-2cf6-4fe5-aa64-6dcae75af98a' User entered '98.1'	System	17 Oct 2020 22:36:46
	System	17 Oct 2020 22:36:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:36:40', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c9ff9af9-2cf6-4fe5-aa64-6dcae75af98a' User entered 'No (N)'	System	17 Oct 2020 22:36:46
	System	17 Oct 2020 22:36:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:36:44', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c9ff9af9-2cf6-4fe5-aa64-6dcae75af98a' User entered '17 Oct 2020 17:36'	System	17 Oct 2020 22:36:46
	System	17 Oct 2020 22:36:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 3'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:35', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3a1d88b4-a50c-4e6f-8e15-00bc0f4340ca' User entered 'Yes (Y)'	System	18 Oct 2020 23:24:49
	System	18 Oct 2020 23:24:49

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:41', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3a1d88b4-a50c-4e6f-8e15-00bc0f4340ca' User entered '95.9'	System	18 Oct 2020 23:24:49
	System	18 Oct 2020 23:24:49

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:44', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3a1d88b4-a50c-4e6f-8e15-00bc0f4340ca' User entered 'No (N)'	System	18 Oct 2020 23:24:49
	System	18 Oct 2020 23:24:49

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:47', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3a1d88b4-a50c-4e6f-8e15-00bc0f4340ca' User entered '18 Oct 2020 18:24'	System	18 Oct 2020 23:24:49
	System	18 Oct 2020 23:24:49

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 4'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:24', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b405b238-2861-418e-b1f4-7332131baa1e' User entered 'Yes (Y)'	System	19 Oct 2020 22:50:39
	System	19 Oct 2020 22:50:39

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:30', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b405b238-2861-418e-b1f4-7332131baa1e' User entered '97.3'	System	19 Oct 2020 22:50:39
	System	19 Oct 2020 22:50:39

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:32', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b405b238-2861-418e-b1f4-7332131baa1e' User entered 'No (N)'	System	19 Oct 2020 22:50:39
	System	19 Oct 2020 22:50:39

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:35', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b405b238-2861-418e-b1f4-7332131baa1e' User entered '19 Oct 2020 17:50'	System	19 Oct 2020 22:50:39
	System	19 Oct 2020 22:50:39

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 5'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:16', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'e1242224-c21f-4f84-85ee-23163657de26' User entered 'Yes (Y)'	System	20 Oct 2020 17:10:46
	System	20 Oct 2020 17:10:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:22', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'e1242224-c21f-4f84-85ee-23163657de26' User entered '98.1'	System	20 Oct 2020 17:10:46
	System	20 Oct 2020 17:10:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:24', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'e1242224-c21f-4f84-85ee-23163657de26' User entered 'No (N)'	System	20 Oct 2020 17:10:46
	System	20 Oct 2020 17:10:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:44', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'e1242224-c21f-4f84-85ee-23163657de26' User entered '20 Oct 2020 12:10'	System	20 Oct 2020 17:10:46
	System	20 Oct 2020 17:10:46

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 6'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:56', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '11b45136-f4b2-49ee-8efb-fb6e3fdf7d04' User entered 'Yes (Y)'	System	22 Oct 2020 11:45:19
	System	22 Oct 2020 11:45:19

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:45:01', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '11b45136-f4b2-49ee-8efb-fb6e3fdf7d04' User entered '98.1'	System	22 Oct 2020 11:45:19
	System	22 Oct 2020 11:45:19

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:45:05', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '11b45136-f4b2-49ee-8efb-fb6e3fdf7d04'	System	22 Oct 2020 11:45:19
User entered 'No (N)'	System	22 Oct 2020 11:45:19

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:45:09', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '11b45136-f4b2-49ee-8efb-fb6e3fdf7d04' User entered '22 Oct 2020 06:45'	System	22 Oct 2020 11:45:19
	System	22 Oct 2020 11:45:19

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 7'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:14', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b763316a-18c2-4456-825d-882d32a07d74'	System	22 Oct 2020 17:44:25
User entered 'Yes (Y)'	System	22 Oct 2020 17:44:25

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:18', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b763316a-18c2-4456-825d-882d32a07d74' User entered '98.3'	System	22 Oct 2020 17:44:25
	System	22 Oct 2020 17:44:25

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:21', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b763316a-18c2-4456-825d-882d32a07d74'	System	22 Oct 2020 17:44:25
User entered 'No (N)'	System	22 Oct 2020 17:44:25

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:24', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b763316a-18c2-4456-825d-882d32a07d74' User entered '22 Oct 2020 12:44'	System	22 Oct 2020 17:44:25
	System	22 Oct 2020 17:44:25

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:39', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c524717b-be48-42ca-a9a9-da88891c4e0e' User entered 'None (1)'	System	16 Oct 2020 15:59:10
	System	16 Oct 2020 15:59:10

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:46', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c524717b-be48-42ca-a9a9-da88891c4e0e' User entered 'No (N)'	System	16 Oct 2020 15:59:10
	System	16 Oct 2020 15:59:10

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:50', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c524717b-be48-42ca-a9a9-da88891c4e0e' User entered 'No (N)'	System	16 Oct 2020 15:59:10
	System	16 Oct 2020 15:59:10

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:54', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c524717b-be48-42ca-a9a9-da88891c4e0e' User entered 'None (1)'	System	16 Oct 2020 15:59:10
	System	16 Oct 2020 15:59:10

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:58:59', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'c524717b-be48-42ca-a9a9-da88891c4e0e' User entered '16 Oct 2020 10:58'	System	16 Oct 2020 15:59:10
	System	16 Oct 2020 15:59:10

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 10:46'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 13:16'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:08:22', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8229fba2-6458-4814-873d-fcd2bce92863'	System	16 Oct 2020 23:08:55
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 23:08:55

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:08:34', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8229fba2-6458-4814-873d-fcd2bce92863' User entered 'No (N)'	System	16 Oct 2020 23:08:55
	System	16 Oct 2020 23:08:55

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:08:39', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8229fba2-6458-4814-873d-fcd2bce92863' User entered 'No (N)'	System	16 Oct 2020 23:08:55
	System	16 Oct 2020 23:08:55

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:08:44', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8229fba2-6458-4814-873d-fcd2bce92863' User entered 'None (1)'	System	16 Oct 2020 23:08:55
	System	16 Oct 2020 23:08:55

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:08:50', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8229fba2-6458-4814-873d-fcd2bce92863' User entered '16 Oct 2020 18:08'	System	16 Oct 2020 23:08:55
	System	16 Oct 2020 23:08:55

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 14:11'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 2'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:36:51', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1cea6b7a-80c9-4b9d-8885-cd45bde6850a'	System	17 Oct 2020 22:37:12
User entered 'Does not interfere with activity (2)'	System	17 Oct 2020 22:37:12

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:36:54', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1cea6b7a-80c9-4b9d-8885-cd45bde6850a' User entered 'No (N)'	System	17 Oct 2020 22:37:12
	System	17 Oct 2020 22:37:12

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:36:57', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1cea6b7a-80c9-4b9d-8885-cd45bde6850a' User entered 'No (N)'	System	17 Oct 2020 22:37:12
	System	17 Oct 2020 22:37:12

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:04', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1cea6b7a-80c9-4b9d-8885-cd45bde6850a' User entered 'None (1)'	System	17 Oct 2020 22:37:12
	System	17 Oct 2020 22:37:12

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:09', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1cea6b7a-80c9-4b9d-8885-cd45bde6850a' User entered '17 Oct 2020 17:37'	System	17 Oct 2020 22:37:12
	System	17 Oct 2020 22:37:12

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 3'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:23:35', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '291805d6-e66e-40c5-88e7-570459456079'	System	18 Oct 2020 23:24:04
User entered 'None (1)'	System	18 Oct 2020 23:24:04

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:23:38', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '291805d6-e66e-40c5-88e7-570459456079' User entered 'No (N)'	System	18 Oct 2020 23:24:04
	System	18 Oct 2020 23:24:04

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:23:42', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '291805d6-e66e-40c5-88e7-570459456079' User entered 'No (N)'	System	18 Oct 2020 23:24:04
	System	18 Oct 2020 23:24:04

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:23:53', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '291805d6-e66e-40c5-88e7-570459456079'	System	18 Oct 2020 23:24:04
User entered 'None (1)'	System	18 Oct 2020 23:24:04

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:01', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '291805d6-e66e-40c5-88e7-570459456079' User entered '18 Oct 2020 18:24'	System	18 Oct 2020 23:24:04
	System	18 Oct 2020 23:24:04

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 4'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:39', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f7c6cf72-001d-45f4-887e-6cc78d843204'	System	19 Oct 2020 22:50:51
User entered 'None (1)'	System	19 Oct 2020 22:50:51

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:41', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f7c6cf72-001d-45f4-887e-6cc78d843204' User entered 'No (N)'	System	19 Oct 2020 22:50:51
	System	19 Oct 2020 22:50:51

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:43', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f7c6cf72-001d-45f4-887e-6cc78d843204' User entered 'No (N)'	System	19 Oct 2020 22:50:51
	System	19 Oct 2020 22:50:51

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:46', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f7c6cf72-001d-45f4-887e-6cc78d843204'	System	19 Oct 2020 22:50:51
User entered 'None (1)'	System	19 Oct 2020 22:50:51

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:49', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f7c6cf72-001d-45f4-887e-6cc78d843204' User entered '19 Oct 2020 17:50'	System	19 Oct 2020 22:50:51
	System	19 Oct 2020 22:50:51

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 5'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:47', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '256e961f-1e88-45bb-b792-9f855864f5ef' User entered 'None (1)'	System	20 Oct 2020 17:11:05
	System	20 Oct 2020 17:11:05

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:49', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '256e961f-1e88-45bb-b792-9f855864f5ef' User entered 'No (N)'	System	20 Oct 2020 17:11:05
	System	20 Oct 2020 17:11:05

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:52', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '256e961f-1e88-45bb-b792-9f855864f5ef' User entered 'No (N)'	System	20 Oct 2020 17:11:05
	System	20 Oct 2020 17:11:05

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:54', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '256e961f-1e88-45bb-b792-9f855864f5ef' User entered 'None (1)'	System	20 Oct 2020 17:11:05
	System	20 Oct 2020 17:11:05

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:10:59', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '256e961f-1e88-45bb-b792-9f855864f5ef' User entered '20 Oct 2020 12:10'	System	20 Oct 2020 17:11:05
	System	20 Oct 2020 17:11:05

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 6'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:18', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3d808756-c141-4fe4-9e1e-3d952dd0dad9'	System	22 Oct 2020 11:44:38
User entered 'None (1)'	System	22 Oct 2020 11:44:38

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:20', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3d808756-c141-4fe4-9e1e-3d952dd0dad9' User entered 'No (N)'	System	22 Oct 2020 11:44:38
	System	22 Oct 2020 11:44:38

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:22', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3d808756-c141-4fe4-9e1e-3d952dd0dad9' User entered 'No (N)'	System	22 Oct 2020 11:44:38
	System	22 Oct 2020 11:44:38

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:24', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3d808756-c141-4fe4-9e1e-3d952dd0dad9'	System	22 Oct 2020 11:44:38
User entered 'None (1)'	System	22 Oct 2020 11:44:38

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:27', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '3d808756-c141-4fe4-9e1e-3d952dd0dad9' User entered '22 Oct 2020 06:44'	System	22 Oct 2020 11:44:38
	System	22 Oct 2020 11:44:38

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 7'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:27', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '4b8f8469-434c-4d42-b316-58dd075f8574' User entered 'None (1)'	System	22 Oct 2020 17:44:39
	System	22 Oct 2020 17:44:39

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:29', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '4b8f8469-434c-4d42-b316-58dd075f8574' User entered 'No (N)'	System	22 Oct 2020 17:44:39
	System	22 Oct 2020 17:44:39

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:30', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '4b8f8469-434c-4d42-b316-58dd075f8574' User entered 'No (N)'	System	22 Oct 2020 17:44:39
	System	22 Oct 2020 17:44:39

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:32', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '4b8f8469-434c-4d42-b316-58dd075f8574'	System	22 Oct 2020 17:44:39
User entered 'None (1)'	System	22 Oct 2020 17:44:39

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:36', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '4b8f8469-434c-4d42-b316-58dd075f8574' User entered '22 Oct 2020 12:44'	System	22 Oct 2020 17:44:39
	System	22 Oct 2020 17:44:39

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:06', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered 'None (0)'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:09', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered 'None (0)'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:12', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered 'None (0)'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:14', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered 'None (0)'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:17', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered 'None (0)'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:19', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered 'None (0)'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:23', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered 'No (N)'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T10:59:26', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8e169fda-4b13-45c8-8c2e-f353e1b8da3e' User entered '16 Oct 2020 10:59'	System	16 Oct 2020 15:59:35
	System	16 Oct 2020 15:59:35

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 10:46'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 13:16'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:08:58', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered 'None (0)'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:09:05', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered 'None (0)'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:09:09', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered 'None (0)'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:09:13', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered 'None (0)'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:09:15', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered 'None (0)'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:09:17', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered 'None (0)'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:09:22', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered 'No (N)'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-16T18:09:26', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'bcae4e81-a9f2-426c-a2af-7e5ae16fea9c' User entered '16 Oct 2020 18:09'	System	16 Oct 2020 23:09:29
	System	16 Oct 2020 23:09:29

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '16 Oct 2020 14:11'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 2'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:14', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered 'None (0)'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:17', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered 'None (0)'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:19', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered 'None (0)'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:21', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered 'None (0)'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:23', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered 'None (0)'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:25', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered 'None (0)'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:27', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered 'No (N)'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-17T17:37:31', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '86f12606-cc1d-45e5-8ab0-f9b68ab759b2' User entered '17 Oct 2020 17:37'	System	17 Oct 2020 22:37:34
	System	17 Oct 2020 22:37:34

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 3'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:05', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered 'None (0)'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:08', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered 'None (0)'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:10', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered 'None (0)'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:12', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered 'None (0)'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:14', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered 'None (0)'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:16', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered 'None (0)'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:18', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered 'No (N)'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-18T18:24:21', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '1e04e100-8979-45fb-8040-fafbd72a6dad' User entered '18 Oct 2020 18:24'	System	18 Oct 2020 23:24:23
	System	18 Oct 2020 23:24:23

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 4'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:52', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7' User entered 'None (0)'	System	19 Oct 2020 22:51:07
	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:54', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7' User entered 'None (0)'	System	19 Oct 2020 22:51:07
	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:56', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7' User entered 'None (0)'	System	19 Oct 2020 22:51:07
	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:57', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7' User entered 'None (0)'	System	19 Oct 2020 22:51:07
	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:50:58', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7' User entered 'None (0)'	System	19 Oct 2020 22:51:07
	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:51:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7' User entered 'None (0)'	System	19 Oct 2020 22:51:07
	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:51:03', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7'	System	19 Oct 2020 22:51:07
User entered 'No (N)'	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-19T17:51:05', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'fe293e17-6b75-4fe4-b4c1-d5deca3ba4a7' User entered '19 Oct 2020 17:51'	System	19 Oct 2020 22:51:07
	System	19 Oct 2020 22:51:07

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 5'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:02', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered 'None (0)'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:04', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered 'None (0)'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:05', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered 'None (0)'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:07', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered 'None (0)'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:08', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered 'None (0)'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:10', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered 'None (0)'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:12', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered 'No (N)'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-20T12:11:16', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'eb02fcae-2b1a-44f1-90bb-754b81ebcd55' User entered '20 Oct 2020 12:11'	System	20 Oct 2020 17:11:20
	System	20 Oct 2020 17:11:20

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 6'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:31', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bffa14b7-8cc4-4604-b7bd-eca33e725682' User entered 'None (0)'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:33', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bffa14b7-8cc4-4604-b7bd-eca33e725682' User entered 'None (0)'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:35', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bffa14b7-8cc4-4604-b7bd-eca33e725682' User entered 'None (0)'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:37', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bffa14b7-8cc4-4604-b7bd-eca33e725682' User entered 'None (0)'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:38', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bffa14b7-8cc4-4604-b7bd-eca33e725682' User entered 'None (0)'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:40', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bff14b7-8cc4-4604-b7bd-eca33e725682' User entered 'None (0)'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:42', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bffa14b7-8cc4-4604-b7bd-eca33e725682' User entered 'No (N)'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T06:44:44', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '2bffa14b7-8cc4-4604-b7bd-eca33e725682' User entered '22 Oct 2020 06:44'	System	22 Oct 2020 11:45:17
	System	22 Oct 2020 11:45:17

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
Data entry locked.	System	16 Oct 2020 15:38:21
User entered 'Day 7'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:39', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered 'None (0)'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:41', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered 'None (0)'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:42', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered 'None (0)'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:44', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered 'None (0)'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:46', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered 'None (0)'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:48', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered 'None (0)'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

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 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:50', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered 'No (N)'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-10-22T12:44:55', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '7bf1812e-6027-4a3d-8234-2fc3e5b7b8b3' User entered '22 Oct 2020 12:44'	System	22 Oct 2020 17:44:58
	System	22 Oct 2020 17:44:58

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 15:38:21

US3862286

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:34:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:42:24
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 15:38:21

US3862286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	23 Oct 2020 22:17:56

US3862286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '23 Oct 2020'	(b) (4) Chanei Henry (b) (4)	23 Oct 2020 22:17:56

US3862286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	23 Oct 2020 22:17:56

US3862286

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	23 Oct 2020 22:17:56
	(b) (4)	

US3862286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	23 Oct 2020 22:18:47

US3862286

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '1'	System	23 Oct 2020 22:18:47

US3862286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 19:26:02

US3862286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:12
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:26:02

US3862286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:26:02

US3862286

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:12
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 19:26:02

US3862286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:12
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Nov 2020 22:08:30

US3862286

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'I'	System	02 Nov 2020 22:08:30

US3862286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 22:43:05

US3862286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 22:43:05

US3862286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 22:43:05

US3862286

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 22:43:05

US3862286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:12
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 22:43:10

US3862286

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'I'	System	06 Nov 2020 22:43:10

US3862286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:00

US3862286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '18 Nov 2020'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:00
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Clinic (Clinic)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:00
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'VISIT2'	System	18 Nov 2020 22:06:00

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Pre-Dose (PREDOSE)'	Chaneí Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '18 Nov 2020'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '15:38'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '18 Nov 2020 15:38'	System	18 Nov 2020 22:06:50

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
	(b) (4)	
User entered '98.0' F	Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Other (Other)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'temporal'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '58'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'bpm'	System	18 Nov 2020 22:06:50

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '14'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'breaths/min'	System	18 Nov 2020 22:06:50

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '98'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:06:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'mmHg'	System	18 Nov 2020 22:06:50

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
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 17:29:28
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 subject is a jogger' (Site from System).	Chanei Henry (b) (4) (b) (4)	18 Nov 2020 22:07:51
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).		18 Nov 2020 22:06:50
User entered '57'	Chanei Henry (b) (4) (b) (4)	18 Nov 2020 22:06:50

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'mmHg'	System	18 Nov 2020 22:06:50

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Post-Dose (POSTDOSE)'	Chaneí Henry (b) (4) (b) (4)	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:08:01

US3862286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	18 Nov 2020 22:09:49
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:09:49

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:13
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
	(b) (4)	
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Chanei Henry (b) (4)	18 Nov 2020 22:10:13
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:13
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:10:13

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:13

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:13
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:10:13

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:13
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:10:13

US3862286

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:10:13

US3862286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:30
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '18 Nov 2020'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:30
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '15:48'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:30
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '18 Nov 2020 15:48'	System	18 Nov 2020 22:10:30

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:34:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '18 Nov 2020'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:45
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chaneí Henry (b) (4) (b) (4)	18 Nov 2020 22:10:45

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:45
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:45

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered empty.	System	18 Nov 2020 22:10:45

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chaneil Henry (b) (4) (b) (4)	18 Nov 2020 22:10:45

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:45
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '15:44'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:45
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '18 Nov 2020 15:44'	System	18 Nov 2020 22:10:45

US3862286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:10:50
	(b) (4)	

US3862286

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '1'	System	18 Nov 2020 22:10:50

US3862286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Nov 2020 22:17:44

US3862286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered '20 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Nov 2020 22:17:44

US3862286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Nov 2020 22:17:44

US3862286

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Nov 2020 22:17:44

US3862286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:42
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Nov 2020 22:17:47

US3862286

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'I'	System	20 Nov 2020 22:17:47

US3862286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:20

US3862286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '30 Nov 2020'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:20

US3862286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:20

US3862286

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:20

US3862286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:24

US3862286

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'I'	System	04 Dec 2020 19:22:24

US3862286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:37

US3862286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered '04 Dec 2020'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:37

US3862286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:37

US3862286

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered empty.	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:37

US3862286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	04 Dec 2020 19:22:41

US3862286

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'I'	System	04 Dec 2020 19:22:41

US3862286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 01:18:43
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	12 Jan 2021 23:18:41

US3862286

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered '1'	System	12 Jan 2021 23:18:41

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-12-27T12:01:33', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '24b85696-33bf-44ba-a6b2-b505c565327f' User entered 'No (N)'	System	27 Dec 2020 18:01:53
	System	27 Dec 2020 18:01:53

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-12-27T12:01:39', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '24b85696-33bf-44ba-a6b2-b505c565327f' User entered 'No (N)'	System	27 Dec 2020 18:01:53
	System	27 Dec 2020 18:01:53

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2020-12-27T12:01:50', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '24b85696-33bf-44ba-a6b2-b505c565327f' User entered '27 Dec 2020 12:01:50'	System	27 Dec 2020 18:01:53
	System	27 Dec 2020 18:01:53

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-03T06:36:34', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b0a0bf3e-ea43-4d6b-8ab3-89628fff7aa3'	System	03 Jan 2021 12:36:53
User entered 'No (N)'	System	03 Jan 2021 12:36:53

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-03T06:36:41', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b0a0bf3e-ea43-4d6b-8ab3-89628fff7aa3'	System	03 Jan 2021 12:36:53
User entered 'No (N)'	System	03 Jan 2021 12:36:53

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-03T06:36:51', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'b0a0bf3e-ea43-4d6b-8ab3-89628fff7aa3' User entered '03 Jan 2021 06:36:51'	System	03 Jan 2021 12:36:53

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-20T18:01:21', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'd248adfc-c265-468b-9aea-1bd47886cd04' User entered 'No (N)'	System	21 Jan 2021 00:01:50
	System	21 Jan 2021 00:01:50

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-20T18:01:26', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'd248adfc-c265-468b-9aea-1bd47886cd04'	System	21 Jan 2021 00:01:50
User entered 'No (N)'	System	21 Jan 2021 00:01:50

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-20T18:01:31', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'd248adfc-c265-468b-9aea-1bd47886cd04' User entered '20 Jan 2021 18:01:31'	System	21 Jan 2021 00:01:50
	System	21 Jan 2021 00:01:50

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-24T08:24:23', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8448931c-de78-4305-bf0f-cfcabb052ebb' User entered 'No (N)'	System	24 Jan 2021 14:24:36
	System	24 Jan 2021 14:24:36

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-24T08:24:28', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8448931c-de78-4305-bf0f-cfcabb052ebb' User entered 'No (N)'	System	24 Jan 2021 14:24:36
	System	24 Jan 2021 14:24:36

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-24T08:24:33', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8448931c-de78-4305-bf0f-cfcabb052ebb' User entered '24 Jan 2021 08:24:33'	System	24 Jan 2021 14:24:36
	System	24 Jan 2021 14:24:36

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-31T10:51:55', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '5c16455b-a877-44fc-8dfc-6d2330754245' User entered 'No (N)'	System	31 Jan 2021 16:52:07
	System	31 Jan 2021 16:52:07

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-31T10:51:57', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '5c16455b-a877-44fc-8dfc-6d2330754245' User entered 'No (N)'	System	31 Jan 2021 16:52:07

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-01-31T10:52:01', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '5c16455b-a877-44fc-8dfc-6d2330754245' User entered '31 Jan 2021 10:52:01'	System	31 Jan 2021 16:52:07
	System	31 Jan 2021 16:52:07

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-07T07:53:36', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '064b44bf-218b-4f72-873b-f5bbea450198'	System	07 Feb 2021 13:53:48
User entered 'No (N)'	System	07 Feb 2021 13:53:48

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-07T07:53:41', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '064b44bf-218b-4f72-873b-f5bbea450198' User entered 'No (N)'	System	07 Feb 2021 13:53:48
	System	07 Feb 2021 13:53:48

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-07T07:53:44', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '064b44bf-218b-4f72-873b-f5bbea450198' User entered '07 Feb 2021 07:53:44'	System	07 Feb 2021 13:53:48
	System	07 Feb 2021 13:53:48

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-14T09:14:55', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '50e98ffb-df3e-40b3-b50f-2a1019d85004'	System	25 Feb 2021 00:03:04
User entered 'No (N)'	System	25 Feb 2021 00:03:04

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-14T09:15:02', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '50e98ffb-df3e-40b3-b50f-2a1019d85004'	System	25 Feb 2021 00:03:04
User entered 'No (N)'	System	25 Feb 2021 00:03:04

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-14T09:15:06', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '50e98ffb-df3e-40b3-b50f-2a1019d85004'	System	25 Feb 2021 00:03:04
User entered '14 Feb 2021 09:15:06'	System	25 Feb 2021 00:03:04

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-24T18:01:26-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '34041822-c69f-4ad2-86aa-6b98f38be189' User entered 'No (N)'	System	25 Feb 2021 00:03:18
	System	25 Feb 2021 00:03:18

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-24T18:01:30-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '34041822-c69f-4ad2-86aa-6b98f38be189'	System	25 Feb 2021 00:03:18
User entered 'No (N)'	System	25 Feb 2021 00:03:18

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-02-24T18:01:33-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '34041822-c69f-4ad2-86aa-6b98f38be189' User entered '25 Feb 2021 00:01:33'	System	25 Feb 2021 00:03:18
	System	25 Feb 2021 00:03:18

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-02T12:00:58-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8c640d55-c64f-4bbf-9428-1639b6f90863'	System	02 Mar 2021 18:02:19
User entered 'No (N)'	System	02 Mar 2021 18:02:19

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-02T12:01:01-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8c640d55-c64f-4bbf-9428-1639b6f90863'	System	02 Mar 2021 18:02:19
User entered 'No (N)'	System	02 Mar 2021 18:02:19

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-02T12:01:05-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '8c640d55-c64f-4bbf-9428-1639b6f90863' User entered '02 Mar 2021 12:01:05'	System	02 Mar 2021 18:02:19
	System	02 Mar 2021 18:02:19

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-09T12:05:15-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '18d54f9d-b394-4880-bb38-5647cf913c1a'	System	09 Mar 2021 18:09:30
User entered 'No (N)'	System	09 Mar 2021 18:09:30

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-09T12:05:17-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '18d54f9d-b394-4880-bb38-5647cf913c1a'	System	09 Mar 2021 18:09:30
User entered 'No (N)'	System	09 Mar 2021 18:09:30

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-09T12:05:22-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '18d54f9d-b394-4880-bb38-5647cf913c1a' User entered '09 Mar 2021 12:05:22'	System	09 Mar 2021 18:09:30
	System	09 Mar 2021 18:09:30

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-16T12:30:38-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '75e0b08e-53cf-4a9d-b782-00bc0bca064e' User entered 'No (N)'	System	16 Mar 2021 17:30:51
	System	16 Mar 2021 17:30:51

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-16T12:30:45-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '75e0b08e-53cf-4a9d-b782-00bc0bca064e'	System	16 Mar 2021 17:30:51
User entered 'No (N)'	System	16 Mar 2021 17:30:51

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-16T12:30:48-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '75e0b08e-53cf-4a9d-b782-00bc0bca064e' User entered '16 Mar 2021 12:30:48'	System	16 Mar 2021 17:30:51
	System	16 Mar 2021 17:30:51

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-23T12:17:42-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'e3681590-7d4b-4583-9a35-a539d4f6f28b'	System	23 Mar 2021 17:17:55
User entered 'No (N)'	System	23 Mar 2021 17:17:55

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-23T12:17:45-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'e3681590-7d4b-4583-9a35-a539d4f6f28b'	System	23 Mar 2021 17:17:55
User entered 'No (N)'	System	23 Mar 2021 17:17:55

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-23T12:17:48-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'e3681590-7d4b-4583-9a35-a539d4f6f28b' User entered '23 Mar 2021 12:17:48'	System	23 Mar 2021 17:17:55
	System	23 Mar 2021 17:17:55

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-28T07:43:42-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f9b7c8dd-7edf-4f47-87fa-de8d8f36da0e'	System	28 Mar 2021 12:43:48
User entered 'No (N)'	System	28 Mar 2021 12:43:48

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-28T07:43:44-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f9b7c8dd-7edf-4f47-87fa-de8d8f36da0e'	System	28 Mar 2021 12:43:48
User entered 'No (N)'	System	28 Mar 2021 12:43:48

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-28T07:43:46-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'f9b7c8dd-7edf-4f47-87fa-de8d8f36da0e' User entered '28 Mar 2021 07:43:46'	System	28 Mar 2021 12:43:48
	System	28 Mar 2021 12:43:48

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-04T11:16:32-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'ca6d9a38-666b-41b0-9839-9cf25a7a6f6f'	System	04 Apr 2021 16:16:40
User entered 'No (N)'	System	04 Apr 2021 16:16:40

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-04T11:16:34-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'ca6d9a38-666b-41b0-9839-9cf25a7a6f6f'	System	04 Apr 2021 16:16:40
User entered 'No (N)'	System	04 Apr 2021 16:16:40

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-04T11:16:37-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'ca6d9a38-666b-41b0-9839-9cf25a7a6f6f'	System	04 Apr 2021 16:16:40
User entered '04 Apr 2021 11:16:37'	System	04 Apr 2021 16:16:40

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-12T07:14:47-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '0e669592-2c61-4abe-a72f-6e8e2130ba32'	System	12 Apr 2021 12:14:57
User entered 'No (N)'	System	12 Apr 2021 12:14:57

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-12T07:14:51-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '0e669592-2c61-4abe-a72f-6e8e2130ba32'	System	12 Apr 2021 12:14:57
User entered 'No (N)'	System	12 Apr 2021 12:14:57

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-12T07:14:53-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '0e669592-2c61-4abe-a72f-6e8e2130ba32'	System	12 Apr 2021 12:14:57
User entered '12 Apr 2021 07:14:53'	System	12 Apr 2021 12:14:57

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-19T06:59:16-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '27400321-492e-4e0f-9571-bd0701fc475d' User entered 'No (N)'	System	19 Apr 2021 11:59:27
	System	19 Apr 2021 11:59:27

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-19T06:59:19-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '27400321-492e-4e0f-9571-bd0701fc475d' User entered 'No (N)'	System	19 Apr 2021 11:59:27

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-19T06:59:21-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '27400321-492e-4e0f-9571-bd0701fc475d' User entered '19 Apr 2021 06:59:21'	System	19 Apr 2021 11:59:27
	System	19 Apr 2021 11:59:27

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-25T07:40:19-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'd51af004-048b-4297-aab7-dc63943a2de1'	System	25 Apr 2021 12:40:27
User entered 'No (N)'	System	25 Apr 2021 12:40:27

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-25T07:40:21-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'd51af004-048b-4297-aab7-dc63943a2de1'	System	25 Apr 2021 12:40:27
User entered 'No (N)'	System	25 Apr 2021 12:40:27

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-04-25T07:40:24-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: 'd51af004-048b-4297-aab7-dc63943a2de1' User entered '25 Apr 2021 07:40:24'	System	25 Apr 2021 12:40:27
	System	25 Apr 2021 12:40:27

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-05-02T19:06:37-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '085f916d-a293-4301-96f9-b27322211803'	System	03 May 2021 00:06:51
User entered 'No (N)'	System	03 May 2021 00:06:51

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

Have you been exposed to someone with 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 (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-05-02T19:06:38-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '085f916d-a293-4301-96f9-b27322211803'	System	03 May 2021 00:06:51
User entered 'No (N)'	System	03 May 2021 00:06:51

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-05-02T19:06:41-05:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '085f916d-a293-4301-96f9-b27322211803'	System	03 May 2021 00:06:51
User entered '02 May 2021 19:06:41'	System	03 May 2021 00:06:51

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 12:55:15

US3862286

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:34:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:55:15
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 12:55:15

US3862286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:34:47

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 20:42:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-02T12:01:11-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '001936e9-0147-4580-9d7e-0c4fdc743fc7'	System	02 Mar 2021 18:02:41
User entered 'No (N)'	System	02 Mar 2021 18:02:41

US3862286

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:34:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:42:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4BC907F8-A884-4E3F-8DF6-037E24D3266C)', Time: '2021-03-02T12:01:15-06:00', User OID: 'PatientReportedOutcome (US3862286)', ODM File OID: '001936e9-0147-4580-9d7e-0c4fdc743fc7'	System	02 Mar 2021 18:02:41
User entered '02 Mar 2021 12:01:15'	System	02 Mar 2021 18:02:41

US3862286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	12 Jan 2021 23:31:43

US3862286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered '12 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	12 Jan 2021 23:31:43

US3862286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	12 Jan 2021 23:31:43

US3862286

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	12 Jan 2021 23:31:43

US3862286

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:37:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	12 Jan 2021 23:31:50

US3862286

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:39:16
User entered 'I'	System	12 Jan 2021 23:31:50

US3862286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Feb 2021 15:01:41

US3862286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered '10 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Feb 2021 15:01:41

US3862286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Feb 2021 15:01:41

US3862286

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Feb 2021 15:01:41

US3862286

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	10 Feb 2021 15:01:46

US3862286

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User entered '1'	System	10 Feb 2021 15:01:46

US3862286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	15 Mar 2021 14:29:12

US3862286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered '15 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	15 Mar 2021 14:29:12

US3862286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	15 Mar 2021 14:29:12

US3862286

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	15 Mar 2021 14:29:12

US3862286

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	15 Mar 2021 14:29:15

US3862286

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:59:27
User entered 'I'	System	15 Mar 2021 14:29:15

US3862286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:15
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:40:17
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	09 Apr 2021 18:08:35

US3862286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:15
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:40:17
User entered '9 Apr 2021'	(b) (4) Shetel Anassi (b) (4)	09 Apr 2021 18:08:35

US3862286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:15
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:40:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shetel Anassi (b) (4)	09 Apr 2021 18:08:35

US3862286

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:15
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:40:17
User entered empty.	(b) (4) Shetel Anassi (b) (4)	09 Apr 2021 18:08:35
	(b) (4)	

US3862286

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:15
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:40:17
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	09 Apr 2021 18:08:40

US3862286

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:15
User entered 'I'	System	09 Apr 2021 18:08:40

US3862286

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:26

US3862286

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:26

US3862286

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Apr 2021 16:17:26

US3862286

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Apr 2021 16:17:26

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 16:17:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
	(b) (4)	
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	30 Apr 2021 16:18:20
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	30 Apr 2021 16:18:06
User entered 'No (N)'	(b) (4), (b) (6)	30 Apr 2021 16:18:06

US3862286

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 16:18:20
User entered '30 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 16:18:06

US3862286

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 16:18:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:18:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:43
User entered '10:59'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 16:18:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021 10:59'	System	30 Apr 2021 16:18:58

US3862286

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	03 May 2021 15:46:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:52:15

US3862286

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 18:52:15

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '2 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	02 Nov 2020 22:22:30

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '14:30' reason for change: Data Entry Error	(b) (4)	
	Thea Marie Cordero	04 Nov 2020 18:58:23
User entered '14:00'	(b) (4)	
	Carrie Kibler (b) (4)	02 Nov 2020 22:22:30
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:49
User entered '2 Nov 2020 14:30'	System	04 Nov 2020 18:58:23
User entered '2 Nov 2020 14:00'	System	02 Nov 2020 22:22:30

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Carrie Kibler (b) (4)	02 Nov 2020 22:22:30

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	02 Nov 2020 22:22:30

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 1 (Day 1)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:45:50
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:49:19
User entered '01 Nov 2020' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:49:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '1 Nov 2020'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:45:50
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:49:13
User entered '0' reason for change: Per Query Resolution	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:49:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '1' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:27:09
User entered '0'	Thea Marie Cordero (b) (4)	04 Nov 2020 19:03:02

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User closed query 'Per CDM: It appears that O2 Saturation was not recorded. If not collected, please consider recording these as NOT DONE ' (Site from DM).		16 Apr 2021 13:29:26
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:45:50
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:49:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Carrie Kibler (b) (4)	15 Apr 2021 20:49:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
Query 'Per CDM: It appears that O2 Saturation was not recorded. If not collected, please consider recording these as NOT DONE ' answered with 'data updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:27:35
User opened query 'Per CDM: It appears that O2 Saturation was not recorded. If not collected, please consider recording these as NOT DONE ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 15:49:23
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 19:03:02

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User entered '%'	System	15 Apr 2021 20:49:13
User entered empty.	System	04 Nov 2020 19:03:02

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '101' F	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Moderate (Moderate)'	Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:03:02
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 2 (Day 2)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '2 Nov 2020'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '99'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User entered '%'	System	04 Nov 2020 19:13:54

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '99.5' F	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:13:54
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 3 (Day 3)'	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:57:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:57:32
User entered '3 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:57:19
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:19

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '97' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 22:28:00
User entered empty.	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:19

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User entered '%'	System	04 Nov 2020 22:28:00
User entered empty.	System	04 Nov 2020 21:57:19

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '100.6' F reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 22:28:00
	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 22:28:00
	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 22:28:00
	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:28:00
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 4 (Day 4)'	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '4 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:32

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '99' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:58:45
User entered empty.	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:32

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User entered '%'	System	04 Nov 2020 21:58:45
User entered empty.	System	04 Nov 2020 21:57:32

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '99.8' F reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:58:45
User entered empty.	(b) (4) Carrie Kibler (b) (4)	04 Nov 2020 21:57:32

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:58:45
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 22:18:05
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 22:18:05
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:58:45
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:58:45
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:58:45
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:58:45
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 22:18:05
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 22:18:05
User entered empty.	Carrie Kibler (b) (4)	04 Nov 2020 21:57:32
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 5 (Day 5)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '5 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User entered '%'	System	05 Nov 2020 22:13:48

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '100.2' F	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 22:13:48

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:13:48
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 6 (Day 6)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User entered '%'	System	11 Nov 2020 23:18:33

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '100.3' F	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	11 Nov 2020 23:18:33

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Moderate (Moderate)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	11 Nov 2020 23:18:33

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:08:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	11 Nov 2020 23:18:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '2 Nov 2020'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[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 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[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 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:18:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 23:18:55
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	11 Nov 2020 23:18:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 19:14:19
User entered empty.	Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '2 Nov 2020'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[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 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 23:18:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 23:18:55
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	11 Nov 2020 23:18:55
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 19:14:19
User entered empty.	Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	04 Nov 2020 19:14:19
	(b) (4)	

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Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:03
User entered '0'	System	11 Nov 2020 23:18:55

US3862286

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:34:47

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per CDM: Site indicates data was corrected; however, it is still blank. Please select "yes" or "no". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 14:06:54
Query 'Per CDM: Site indicates data was corrected; however, it is still blank. Please select "yes" or "no". Thank you.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	17 Nov 2020 21:48:39
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	17 Nov 2020 21:48:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 18:47:43
User opened query 'Per CDM: Site indicates data was corrected; however, it is still blank. Please select "yes" or "no". Thank you.' (Site from DM).		16 Nov 2020 18:47:19
Query 'Data is required. Please complete.' answered with 'data corrected' (Site from System).	Carrie Kibler (b) (4) (b) (4)	02 Nov 2020 22:22:49
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 22:22:42
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	02 Nov 2020 22:22:42
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	02 Nov 2020 22:22:34

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:10
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '15:10'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:10
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:20
User entered '16 Dec 2020 15:10'	System	18 Dec 2020 19:04:10

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:10

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:34:47

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:10

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 1 (Day 1)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:13:41
User entered '09 Dec 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:13:41
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered '9 Dec 2020'	Hana El Sahly (b) (4)	18 Dec 2020 19:07:11
	Thea Marie Cordero (b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:13:41
User entered '0' reason for change: Per Query Resolution	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '1' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:28:46
User entered '0'	Thea Marie Cordero (b) (4)	18 Dec 2020 19:07:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
User closed query 'Per CDM Re-Query: Site response noted; however Assessment Day 1 was completed. Please consider UNCHECKING "Assessment Not Done" box. Please consider updating O2 and Temperature with "ND-Not Done" if they were not collected. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 11:26:54
Query 'Per CDM Re-Query: Site response noted; however Assessment Day 1 was completed. Please consider UNCHECKING "Assessment Not Done" box. Please consider updating O2 and Temperature with "ND-Not Done" if they were not collected. Thank you.' answered with 'updated in edc.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	19 Apr 2021 21:14:01
Signature has been broken.	Carrie Kibler (b) (4) (b) (4)	19 Apr 2021 21:13:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	19 Apr 2021 21:13:41
User opened query 'Per CDM Re-Query: Site response noted; however Assessment Day 1 was completed. Please consider UNCHECKING "Assessment Not Done" box. Please consider updating O2 and Temperature with "ND-Not Done" if they were not collected. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:30:52
User closed query 'Per CDM: If the O2 Saturation and Temperature were not done (for log lines 1-7), please consider recording these data points as "Not Done". Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:30:52
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:45:23
Query 'Per CDM: If the O2 Saturation and Temperature were not done (for log lines 1-7), please consider recording these data points as "Not Done". Thank you.' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:29:35

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: If the O2 Saturation and Temperature were not done (for log lines 1-7), please consider recording these data points as "Not Done". Thank you. ' (Site from DM). User entered empty.	(b) (4), (b) (6) (b) (4)	02 Feb 2021 11:15:41
	Thea Marie Cordero (b) (4)	18 Dec 2020 19:07:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	19 Apr 2021 21:13:41
User entered empty.	System	18 Dec 2020 19:07:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:13:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:13:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:07:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 2 (Day 2)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '10 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:16:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:16:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	19 Apr 2021 21:16:03
User entered empty.	System	18 Dec 2020 19:08:07

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:16:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:16:03
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:08:07
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 3 (Day 3)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '11 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:16:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:16:50
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:08:54
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	19 Apr 2021 21:16:50
User entered empty.	System	18 Dec 2020 19:08:54

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:16:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:16:50
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:08:54
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:08:54
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 4 (Day 4)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '12 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:17:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:17:19
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:09:41
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	19 Apr 2021 21:17:19
User entered empty.	System	18 Dec 2020 19:09:41

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:17:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:17:19
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:09:41
	Thea Marie Cordero (b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:09:41
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 5 (Day 5)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '13 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:17:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:17:47
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:10:34
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	19 Apr 2021 21:17:47
User entered empty.	System	18 Dec 2020 19:10:34

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:17:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:17:47
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:10:34
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:10:34
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 6 (Day 6)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '14 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:18:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	19 Apr 2021 21:18:21
User entered empty.	System	18 Dec 2020 19:11:24

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:18:21
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Carrie Kibler (b) (4)	19 Apr 2021 21:18:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:11:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 7 (Day 7)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '15 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:19:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:19:07
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:14:50
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	19 Apr 2021 21:19:07
User entered empty.	System	18 Dec 2020 19:14:50

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
Signature has been broken.	(b) (4)	19 Apr 2021 21:19:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Carrie Kibler (b) (4)	19 Apr 2021 21:19:07
User signature succeeded.	(b) (4)	02 Apr 2021 14:45:23
User entered empty.	Hana El Sahly (b) (4)	18 Dec 2020 19:14:50
	Thea Marie Cordero (b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:14:50
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 8 (Day 8)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '99'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	18 Dec 2020 19:16:05

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98' F	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:16:05
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 9 (Day 9)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '17 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '100'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98.0' F	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	18 Dec 2020 22:22:11

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 10 (Day 10)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '18 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '100'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98.0' F	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Mild (Mild)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	18 Dec 2020 22:38:26

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 11 (Day 11)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '19 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '100'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '97.6' F	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:09:14

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:14

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 12 (Day 12)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '20 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35
	(b) (4)	

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Form: Symptom Log (12)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98.0' F	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

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 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:09:35

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Day 13 (Day 13)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '21 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '100'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User entered '%'	System	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98.4' F	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:34:47

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'None (None)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 22:07:33

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[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 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:28

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[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 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 19:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:16:42
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	21 Dec 2020 19:16:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Dec 2020 19:04:28
User entered empty.	Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[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 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	18 Dec 2020 19:04:28
	(b) (4)	

US3862286

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:34:47

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:09:41
User entered '0'	System	21 Dec 2020 19:16:42

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 10Nov2020 is reported for Day 3 with Accession # 1F650964124 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 06:44:19
Query 'Per GCL Lab Recon: Saliva: Sample dated 10Nov2020 is reported for Day 3 with Accession # 1F650964124 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' answered with 'data correct as is will contact Preclarus portal to change date of collection. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:34:44
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 10Nov2020 is reported for Day 3 with Accession # 1F650964124 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:58:25
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:58:18

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 and 06NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 06:47:25
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 and 06NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 04:19:11
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04NOV2020 and 06NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 10:56:44
User entered '4 Nov 2020'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 06NOV2020 for Day 5 is recorded in EDC, however sample is reported with 10NOV2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:35:21
Query 'Per GCL Lab Recon: Saliva: Sample dated 06NOV2020 for Day 5 is recorded in EDC, however sample is reported with 10NOV2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' answered with '06 NOV is correct' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 21:07:39
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 06NOV2020 for Day 5 is recorded in EDC, however sample is reported with 10NOV2020 for Day 5 in PPD Central lab. Please confirm the correct date and update if applicable, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:47:56
User entered '6 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Carrie Kibler (b) (4) (b) (4)	10 Nov 2020 20:07:39

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Nov 2020 20:07:39
	(b) (4)	

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User accepted default value 'Day 3 (Day 3)'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 23Dec2020 is reported for Day 3 with Accession # 1F640347363 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 06:43:38
Query 'Per GCL Lab Recon: Saliva: Sample dated 23Dec2020 is reported for Day 3 with Accession # 1F640347363 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' answered with 'will contact Preclarus to do date of collection change. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:39:07
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 23Dec2020 is reported for Day 3 with Accession # 1F640347363 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:59:51
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:59:34

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:17:07
User entered '18 Dec 2020'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User accepted default value 'Day 5 (Day 5)'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 23Dec2020 is reported for Day 5 with Accession # 1F657671275 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 05:03:31
Query 'Per GCL Lab Recon: Saliva: Sample dated 23Dec2020 is reported for Day 5 with Accession # 1F657671275 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' answered with 'will contact Preclarus to do date of collection change. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:39:17
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 23Dec2020 is reported for Day 5 with Accession # 1F657671275 in Preclarus portal. Please confirm the correct date and update if applicable in EDC, else update the date in Preclarus portal to reflect correct. Date of collection must be same in both (EDC and PPD Central Lab), thank you.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 07:00:41
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 07:00:37

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20DEC2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 08:19:38
User entered '20 Dec 2020'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User accepted default value 'Day 7 (Day 7)'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User accepted default value 'Day 9 (Day 9)'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:12:08
	(b) (4)	

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User accepted default value 'Day 14 (Day 14)'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User accepted default value 'Day 21 (Day 21)'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User accepted default value 'Day 28 (Day 28)'	Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:47

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:12:08
	(b) (4)	

US3862286

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:12:08

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Nov 2020 23:06:09
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 06:43:20
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'SALIVA SAMPLES: DAY 3 (04/NOV 2020) DAY 4 (06/NOV 2020) WERE COLLECTED ON THESE RESPECTIVE DATES, DOCUMENTED UNDER SALIVA COLLECTION SECTION REFER TO ILLNESS VISIT 02 NOV 2020.	Thea Marie Cordero (b) (4)	18 Dec 2020 20:23:48
PI' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:24:32
User entered '2 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:06:09

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	06 Nov 2020 23:06:09
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	06 Nov 2020 23:06:09

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '2 Nov 2020'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '14:20'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '2 Nov 2020 14:20'	System	06 Nov 2020 23:08:59

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '185' cm	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	
DataPoint set to visible.	System	06 Nov 2020 23:06:09

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '163.8' lb	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	
DataPoint set to visible.	System	06 Nov 2020 23:06:09

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '99.5' F	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Oral (Oral)'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '103'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 23:08:59

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '16'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 23:08:59

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '114'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 23:08:59

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '75'	Carrie Kibler (b) (4)	06 Nov 2020 23:08:59
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 23:08:59

US3862286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Nov 2020 23:09:04
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '2 Nov 2020'	Carrie Kibler (b) (4)	06 Nov 2020 23:09:04
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:34:47

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Nov 2020 23:09:11
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '2 Nov 2020'	Carrie Kibler (b) (4)	06 Nov 2020 23:09:11
	(b) (4)	

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:10:51

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:05:32
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'will contact Preclarus to do date of collection change. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 21:45:10
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 08:19:06
User entered '16 Dec 2020'	Carrie Kibler (b) (4)	21 Dec 2020 19:10:51

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[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 13:21:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:10:51

US3862286

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:09
User entered 'SICKD1'	System	21 Dec 2020 19:10:51

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '15:20'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User entered '16 Dec 2020 15:20'	System	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '185.0' cm	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:11:34
DataPoint set to visible.	(b) (4) System	21 Dec 2020 19:10:51

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '163.8' lb	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:11:34
DataPoint set to visible.	(b) (4) System	21 Dec 2020 19:10:51

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '98.0' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '58'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User entered 'bpm'	System	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '14'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User entered 'breaths/min'	System	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '107'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User entered 'mmHg'	System	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '65'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17
User entered 'mmHg'	System	21 Dec 2020 19:11:34

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17

US3862286

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:17

US3862286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:11:41

US3862286

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:41

US3862286

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:34:47

[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 13:21:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:11:49

US3862286

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:34:47

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:21:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:11:49

US3862286

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:16
	(b) (4)	

US3862286

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:16
	(b) (4)	

US3862286

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[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 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:16
	(b) (4)	

US3862286

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

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 15:00:16

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 15:45:49
	(b) (4)	

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[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 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:52:17

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:45:49
	(b) (4)	

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'AMENDMENT 5 (AMENDMENT 5)'	System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:52:17

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User closed query 'Per DM: Date of unblinding is prior to the date of updated informed consent. Please reconcile. ' (Site from DM).		04 Apr 2021 10:32:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
Query 'Per DM: Date of unblinding is prior to the date of updated informed consent. Please reconcile. ' answered with 'Data is correct.' (Site from DM).	Shetel Anassi (b) (4)	01 Apr 2021 17:40:57
	(b) (4)	
User opened query 'Per DM: Date of unblinding is prior to the date of updated informed consent. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:52:01
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).		01 Apr 2021 05:51:46
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'subject was unblinded before he came in for his open label visit' (Site from System).		23 Mar 2021 21:41:34
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	10 Feb 2021 15:45:49
User entered '17 Dec 2020'	Carrie Kibler (b) (4)	10 Feb 2021 15:45:49
	(b) (4)	

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	10 Feb 2021 15:45:49
	(b) (4)	

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Carrie Kibler (b) (4)	10 Feb 2021 15:45:49
	(b) (4)	

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Not Administered (NA)'	Carrie Kibler (b) (4)	10 Feb 2021 15:45:49
	(b) (4)	

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:45:49
	(b) (4)	

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered empty.	System	10 Feb 2021 15:45:49

US3862286

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

Form: Unblinding

Generated On: 12 Aug 2021 13:34:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'I'	System	10 Feb 2021 15:45:49

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered empty.	System	10 Feb 2021 15:47:13
DataPoint set to visible.	System	10 Feb 2021 15:45:49

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered empty.	System	10 Feb 2021 15:47:13
DataPoint set to visible.	System	10 Feb 2021 15:45:49

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '08:31'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered '10 Feb 2021 08:31'	System	10 Feb 2021 15:47:13

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '97.9' F	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'temporal'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '59' reason for change: Data Entry Error	Carrie Kibler (b) (4)	10 Feb 2021 15:47:26
	(b) (4)	
User entered '60'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'bpm'	System	10 Feb 2021 15:47:13

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '16'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'breaths/min'	System	10 Feb 2021 15:47:13

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '100'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'mmHg'	System	10 Feb 2021 15:47:13

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '69'	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'mmHg'	System	10 Feb 2021 15:47:13

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	10 Feb 2021 15:47:13
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:34:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered empty.	System	10 Feb 2021 15:47:13
DataPoint set to visible.	System	10 Feb 2021 15:45:49

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '11:23'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered '10 Feb 2021 11:23'	System	10 Feb 2021 18:42:39

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '97.9' F	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered 'temporal'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '50'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'bpm'	System	10 Feb 2021 18:42:39

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '14'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'breaths/min'	System	10 Feb 2021 18:42:39

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '108'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'mmHg'	System	10 Feb 2021 18:42:39

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
	(b) (4)	
User entered '61'	Carrie Kibler (b) (4)	10 Feb 2021 18:42:39
	(b) (4)	

US3862286

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'mmHg'	System	10 Feb 2021 18:42:39

US3862286

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:46:32
	(b) (4)	

US3862286

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 15:46:32
	(b) (4)	

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 18:43:20
	(b) (4)	

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Feb 2021 18:43:20
	(b) (4)	

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

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 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	10 Feb 2021 18:43:20
	(b) (4)	

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'mRNA-1273'	System	10 Feb 2021 18:43:20
DataPoint set to visible.	System	10 Feb 2021 15:45:49

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 18:43:20
	(b) (4)	

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10:53'	Carrie Kibler (b) (4)	10 Feb 2021 18:43:20
	(b) (4)	

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered '10 Feb 2021 10:53'	System	10 Feb 2021 18:43:20

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Carrie Kibler (b) (4)	10 Feb 2021 18:43:20
	(b) (4)	

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'ONCE'	System	10 Feb 2021 18:43:20

US3862286

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

Form: Exposure

Generated On: 12 Aug 2021 13:34:47

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 18:43:20

US3862286

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:42
	(b) (4)	

US3862286

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:42
	(b) (4)	

US3862286

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '08:39'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:42
	(b) (4)	

US3862286

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered '10 Feb 2021 08:39'	System	10 Feb 2021 15:00:42

US3862286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:50
	(b) (4)	

US3862286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10 Feb 2021'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:50
	(b) (4)	

US3862286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '08:36'	Carrie Kibler (b) (4)	10 Feb 2021 15:00:50
	(b) (4)	

US3862286

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:34:47

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered '10 Feb 2021 08:36'	System	10 Feb 2021 15:00:50

US3862286

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

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	10 Feb 2021 15:46:40
	(b) (4)	

US3862286

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

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:57:39
User entered 'I'	System	10 Feb 2021 15:46:40

US3862286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:56:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 20:24:09

US3862286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:56:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered '19 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 20:24:09

US3862286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:56:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 20:24:09

US3862286

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:34:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:56:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 20:24:09

US3862286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:56:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:30
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 20:24:13

US3862286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:56:54
User entered 'I'	System	19 Feb 2021 20:24:13

US3862286

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:34:47

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:56:54
User entered '1'	System	19 Feb 2021 20:24:13
DataPoint set to visible.	System	19 Feb 2021 20:24:13

US3862286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:14:20

US3862286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User closed query 'Per GCL Lab Recon: Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 22 MAR 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM). Query 'Per GCL Lab Recon: Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 22 MAR 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' answered with 'PENDING CORRECTION ON PRECLARUS' (Site from DM). User opened query 'Per GCL Lab Recon: Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 22 MAR 2021, as it is updated under OL-D29 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM). User signature succeeded.	Carrie Kibler (b) (4) (b) (4)	16 Apr 2021 14:37:34 15 Apr 2021 21:11:14
User entered '22 Mar 2021'	Hana El Sahly (b) (4) (b) (4) (b) (4), (b) (6)	15 Apr 2021 09:48:58 02 Apr 2021 14:45:23 22 Mar 2021 17:14:20

US3862286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:14:20

US3862286

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:34:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User entered 'OLD29'	System	22 Mar 2021 17:14:20

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '11:28'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User entered '22 Mar 2021 11:28'	System	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '097.7' F	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '050'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User entered 'bpm'	System	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '015'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User entered 'breaths/min'	System	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '111'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User entered 'mmHg'	System	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '064'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User entered 'mmHg'	System	22 Mar 2021 17:17:53

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25

US3862286

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:34:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25

US3862286

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:18:09

US3862286

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:34:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:18:09

US3862286

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:18:28

US3862286

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User closed query 'Per GCL lab Recon: Per Preclarus report, this "OL-2" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).		12 Apr 2021 08:26:37
Query 'Per GCL lab Recon: Per Preclarus report, this "OL-2" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' answered with 'Accession ID :1F60MZT' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	07 Apr 2021 16:41:34
User opened query 'Per GCL lab Recon: Per Preclarus report, this "OL-2" Immuno sample dated is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:58:26
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:45:23
User entered '22 Mar 2021'	(b) (4), (b) (6)	22 Mar 2021 17:18:28

US3862286

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '11:45'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:18:28

US3862286

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:34:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:23:25
User entered '22 Mar 2021 11:45'	System	22 Mar 2021 17:18:28

US3862286

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:34:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:53
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'Yes (Y)'	(b) (4)	04 Nov 2020 18:55:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:32:20
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'SUBJECT WAS ASSESSED, CENTRAL LAB RESULT FOR SARS COV-2 RT PCR: NOT DETECTED 06 NOV 2020' (Site from DM).	Thea Marie Cordero (b) (4)	18 Dec 2020 19:00:52
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 18:04:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 18:04:58
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 18:22:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:07:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:07:43
Data point term sent to Coder	System	13 Nov 2020 22:28:44
User closed query 'For coding purposes, for term VIRAL LIKE ILLNESS, please enter symptoms, one per line' (Site from System).	System	13 Nov 2020 22:27:47
Query 'For coding purposes, for term VIRAL LIKE ILLNESS, please enter symptoms, one per line' answered with 'adverse event will remain as is' (Site from System).	Carrie Kibler (b) (4) (b) (4)	13 Nov 2020 22:27:47
User opened query 'For coding purposes, for term VIRAL LIKE ILLNESS, please enter symptoms, one per line' (Site from System).	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:06:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:13:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:13:27

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	04 Nov 2020 18:57:49
User entered 'Viral like illness'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 18:57:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 18:57:38
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	06 Nov 2020 18:57:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 18:57:35
User entered empty.	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '1 Nov 2020'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:57:35

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 22:16:16
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '11 Nov 2020' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 22:16:16
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 18:57:35

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:23:41
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 18:57:35

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:23:41
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 18:57:35

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:23:41
User entered empty.	Thea Marie Cordero (b) (4)	04 Nov 2020 18:57:35

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered '0'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 22:16:16
	(b) (4)	
User entered 'None (NONE)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:23:41
User entered '0'	Thea Marie Cordero (b) (4)	04 Nov 2020 18:57:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:23:41
User entered '1'	Thea Marie Cordero (b) (4)	04 Nov 2020 18:57:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:23:41
User entered '0'	Thea Marie Cordero (b) (4)	04 Nov 2020 18:57:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 22:16:16
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 18:57:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 18:57:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:34:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 18:57:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:03:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Dec 2020 19:03:51
Data point term sent to Coder	System	18 Dec 2020 19:02:22
User entered 'VIRAL UPPER RESPIRATORY SYMPTOMS'	Thea Marie Cordero	18 Dec 2020 19:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'No (N)'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	18 Dec 2020 19:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:16:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:16:03
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	21 Dec 2020 19:16:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Dec 2020 19:02:15
User entered empty.	System	18 Dec 2020 19:02:15
	Thea Marie Cordero	18 Dec 2020 19:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '9 Dec 2020'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User entered empty.	System	18 Dec 2020 19:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'No (N)' reason for change: New Information	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:16:03
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	18 Dec 2020 19:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '19 Dec 2020' reason for change: New Information	(b) (4)	21 Dec 2020 19:16:03
User entered empty.	Carrie Kibler (b) (4)	18 Dec 2020 19:02:15
	(b) (4)	
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User entered empty.	System	18 Dec 2020 19:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'No (N)'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'Not Related (NOT RELATED)'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'Not Related (NOT RELATED)'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	18 Dec 2020 19:02:15
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'I'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered '0'	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Carrie Kibler (b) (4)	21 Dec 2020 19:16:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Thea Marie Cordero	18 Dec 2020 19:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:23:41
User entered empty.	(b) (4)	18 Dec 2020 19:02:15
	Thea Marie Cordero	
	(b) (4)	

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User entered '0'	System	18 Dec 2020 19:02:15

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16
User entered '0'	System	18 Dec 2020 19:02:15

US3862286

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:34:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:20:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:34:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	16 Oct 2020 18:57:36

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:01:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:01:42
Data point term sent to Coder	System	19 Oct 2020 16:00:37
User entered 'levothyroxine'	Trent Davis (b) (4)	19 Oct 2020 15:59:47

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'hypothyroidism'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '88'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Nov 2020 22:23:24
	(b) (4)	
User entered 'Other (OTHER)'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:46:11
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'data corrected' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	02 Nov 2020 22:23:32
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4) (b) (4)	02 Nov 2020 22:23:24
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:19:54
User entered 'mcg'	Trent Davis (b) (4) (b) (4)	19 Oct 2020 15:59:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'un UNK 2015'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 15:59:47
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:59:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:59:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 15:59:47

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 16:51:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 16:51:36
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 16:50:36
Coding entries removed.	Trent Davis (b) (4)	01 Dec 2020 16:49:56
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:12:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:12:24
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 16:10:56
User entered 'Flonase'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:43:45
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (e.g. seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 12:43:15
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'data corrected' (Site from DM).	Trent Davis (b) (4) (b) (4)	01 Dec 2020 16:50:05
Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (e.g. seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'data corrected' (Site from DM).	Trent Davis (b) (4) (b) (4)	01 Dec 2020 16:50:02
User entered 'Seasonal ALLERGIES' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	01 Dec 2020 16:49:56
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 21:17:55
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (e.g. seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 21:17:00
User entered 'Allergies'	Trent Davis (b) (4) (b) (4)	19 Oct 2020 16:10:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Other (OTHER)'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "puff" from the drop down list. Please update accordingly. Else Clarify. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:58:00
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "puff" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:20:08
User entered 'spray'	Trent Davis (b) (4) (b) (4)	19 Oct 2020 16:10:25

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'un UNK 2014'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 16:10:25
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:10:25

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:10:25

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:10:25

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:28:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:28:21
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 16:27:20
User entered 'Multivitamin'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:44:02
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'data corrected' (Site from DM).	Trent Davis (b) (4) (b) (4)	01 Dec 2020 16:50:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	01 Dec 2020 16:50:18
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 21:20:45
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	19 Oct 2020 16:26:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Prophylaxis for general health'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '1000'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'un UNK 1985'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 16:26:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:26:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:26:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:26:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 22:20:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 22:20:26
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 16:27:19
User entered 'Aspirin'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Melanoma'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '81'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:44:15
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'data is correct subject was taking prior to actual diagnosis' (Site from DM).	Trent Davis (b) (4) (b) (4)	01 Dec 2020 16:51:09
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. '(Site from DM).	(b) (4), (b) (6)	27 Nov 2020 20:40:07
User entered 'un UNK 2010'	Trent Davis (b) (4) (b) (4)	19 Oct 2020 16:27:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 16:27:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:27:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:27:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:27:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Oct 2020 09:41:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 09:41:32
Data point term sent to Coder	System	19 Oct 2020 16:36:30
User entered 'Vitamin C'	Trent Davis (b) (4) (b) (4)	19 Oct 2020 16:35:46

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'ProphylAXIS FOR GENERAL'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '1000'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'UN UNK 1985'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	19 Oct 2020 16:35:46
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:35:46

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:35:46

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:35:46

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 19:39:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 19:39:27
Data point term sent to Coder	System	04 Nov 2020 19:23:35
User entered 'Tylenol'	Thea Marie Cordero (b) (4)	04 Nov 2020 19:23:02

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Viral like illness'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '1000'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'other (OTHER)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'every 6 hours as needed'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '1 Nov 2020'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10 Nov 2020' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 23:21:21
	(b) (4)	
User entered '2 Nov 2020'	Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:02
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User entered empty.	System	04 Nov 2020 19:23:02

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User entered empty.	System	04 Nov 2020 19:23:02

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:50
User entered empty.	System	04 Nov 2020 19:23:02

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:58:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:58:28
Data point term sent to Coder	System	04 Nov 2020 19:24:36
User entered 'Ibuprofen'	Thea Marie Cordero (b) (4)	04 Nov 2020 19:23:52

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'viral like illness'	Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '400'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'other (OTHER)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'every 4-6 hours as needed'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	04 Nov 2020 19:24:06
User entered '3 Nov 2020' reason for change: Data Entry Error	Thea Marie Cordero	04 Nov 2020 19:24:06
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	04 Nov 2020 19:23:52
User entered empty.	Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)' reason for change: New Information	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 23:18:58
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10 Nov 2020' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 23:18:58
	(b) (4)	
User entered empty.	Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Thea Marie Cordero	04 Nov 2020 19:23:52
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User entered empty.	System	04 Nov 2020 19:23:52

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User entered empty.	System	04 Nov 2020 19:23:52

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:55
User entered empty.	System	04 Nov 2020 19:23:52

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: WALGREENS COLD AND FLU RELIEF NIGHTTIME ORIGINAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 06:48:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 06:48:13
Data point term sent to Coder	System	05 Nov 2020 22:22:52
User entered 'Walgreens Cold and Flu Liquid'	Carrie Kibler (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'viral LIKE ILLNESS' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:48
User entered 'flu like illness'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '30'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'mL (mL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'as needed (PRN)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '5 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)' reason for change: New Information	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 23:18:32
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 22:22:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '10 Nov 2020' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 23:18:32
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 22:22:29
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User entered empty.	System	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User entered empty.	System	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:01
User entered empty.	System	05 Nov 2020 22:22:29

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 15:41:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 15:41:57
Data point term sent to Coder Coding entries removed.	System	15 Mar 2021 14:18:17
	Carrie Kibler (b) (4)	15 Mar 2021 14:17:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 23:03:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 23:03:25
Data point term sent to Coder User entered 'zofran'	System	06 Nov 2020 23:02:28
	Carrie Kibler (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4)	26 Apr 2021 14:06:11
	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated in edc and source' (Site from DM).	Carrie Kibler (b) (4)	15 Mar 2021 14:17:35
	(b) (4)	
User entered 'viral like illness' reason for change: Per Query Resolution	Carrie Kibler (b) (4)	15 Mar 2021 14:17:25
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). User entered 'nausea'	(b) (4), (b) (6)	07 Feb 2021 08:04:38
	Carrie Kibler (b) (4)	06 Nov 2020 23:02:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '4'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'other (OTHER)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'every 6 hours as needed'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 23:18:03
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Nov 2020 23:02:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered '9 Nov 2020' reason for change: New Information	Chanei Henry (b) (4)	18 Nov 2020 23:18:03
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	06 Nov 2020 23:02:12
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User entered empty.	System	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User entered empty.	System	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:06
User entered empty.	System	06 Nov 2020 23:02:12

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:13:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:13:34
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX Z-PACK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:33:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:33:24
Data point term sent to Coder	System	06 Nov 2020 23:03:29
User entered 'azithromycin z-pack'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'viral like illness'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '250'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:51
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'twice daily (BID)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:51
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:51
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:51
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:02:51
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User entered '2'	System	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User entered '1'	System	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:20
User entered '804 (804)'	System	06 Nov 2020 23:02:51

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: Z-PAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:13:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:13:34
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:45:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX Z-PACK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:33:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:33:26
Data point term sent to Coder	System	06 Nov 2020 23:03:29
User entered 'azithromycin z-pack'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'viral like illness'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '250'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'once daily (QD)'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:03:27
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:03:27
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered empty.	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:03:27
	(b) (4)	

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)' reason for change: New Information	(b) (4) Carrie Kibler (b) (4)	10 Nov 2020 19:58:51
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '10 Nov 2020' reason for change: New Information	(b) (4)	10 Nov 2020 19:58:51
User entered empty.	Carrie Kibler (b) (4)	06 Nov 2020 23:03:27
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User entered '1'	System	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User entered '1'	System	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:34:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:26
User entered '804 (804)'	System	06 Nov 2020 23:03:27

US3862286

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:34:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Chanei Henry (b) (4)	26 Mar 2021 01:06:05
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:25:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'Visit 3 Day 57 (VISIT3)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:18:23
	(b) (4)	

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

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[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

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[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Dec 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

US3862286

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'ILLNESS VISIT'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'I'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 12 Aug 2021 13:34:47

[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:15:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	21 Dec 2020 19:18:23

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:47

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered '16 Oct 2020'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:14:22
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:47

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:45:23
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) Chanei Henry (b) (4)	18 Nov 2020 22:14:22

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:47

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 05:32:34
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:04:21
User closed query 'Per CDM: Response noted. Per Sponsor review, if subject took a vaccine outside of the study, Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:34:45
Query 'Per CDM: Response noted. Per Sponsor review, if subject took a vaccine outside of the study, Please agree to update the Reason for discontinuation to Protocol Deviation.' answered with 'Subject requested to not receive Part A - Dose 2. As dosing discontinuation only applies to Part A of the study, the entry has been updated in EDC to AE#01.	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 19:16:19
Subject requested to unblind prior to amendment #6, found to have one dose of mRNA-1273, and decided to stay on study to receive second dose of mRNA-1273 on their Open Label Visit. Subject did not receive another vaccine outside of study. ' (Site from DM).		
Signature has been broken.	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 19:08:40
User entered 'AE# 01' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 19:08:40
User opened query 'Per CDM: Response noted. Per Sponsor review, if subject took a vaccine outside of the study, Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 16:34:54
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 16:34:54
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:45:23

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:34:47

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1).' answered with 'Subject requested to be discontinued from study to receive a non study EAU vaccine ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 20:10:55
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:34:12
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 15:33:25
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:22:57
User entered 'Viral like illness [unknown etiology]'	Chanei Henry (b) (4) (b) (4)	18 Nov 2020 22:14:22